

STATE OF MICHIGAN  
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
BUREAU OF HEALTH PROFESSIONS

**FY 2008 REPORT AND RECOMMENDATIONS**  
**OF THE E-HEALTH WORKGROUP**



**MARCH 2008**

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## EXECUTIVE SUMMARY

The use of technology in the delivery of health care has increasingly become a recognized part of the health care industry. Practitioner utilization of various electronic media to deliver information such as the internet, teleconferencing and computerized medical records is now becoming part of how we define “modern health care. With an ever increasing number of technologies available, many state and federal health agencies have pursued a review of this technology and begun to develop a coordinated plan for both the implementation and regulation of these ongoing advancements in technologically facilitated health care delivery. Since 2000, there has been an accelerated recognition of the need to reach a consensus on terms and definitions and develop a more unified approach regarding the use of these technologies at both the state and federal level.

In September 2005, the Bureau of Health Professions convened a workgroup to examine the numerous issues related to the use of these technologies in the delivery of health care in Michigan. To ensure that proper regulation of the use of healthcare technology occurs, and to enhance patient care through an increased use of this technology, the workgroup was charged with the following tasks:

- Review the technologies currently utilized to gather, analyze, store and transmit patient health data.
- Review current federal and Michigan law affecting the use of technology in the provision of health care.
- Review the related positions, activities, and regulations of other states.
- Make recommendations to the Michigan Department of Community Health concerning changes and/or development of administrative rules or statutory law which would allow for increased utilization and proper regulation of technology when addressing health care data.

Between September 2005 and October 2007, the workgroup met a total of five times. These meetings were structured to disseminate materials, build a working vocabulary of terms, identify and explore the issues related to health care technology, examine the benefits, risks and disadvantages of these emerging technologies, and develop recommendations for how our state should implement and regulate these practices.

The following recommendations were determined by the workgroup. They are based on 1) discussions at the workgroup meetings, 2) a review of the professional literature, 3) an online investigation of E-health information, 4) a review of current federal and Michigan law affecting E-Health, and 5) E-Health policies and statutes of other states.

1. MDCH should adopt the Federation of State Medical Board’s *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* and communicate this to all health care providers through appropriate Department websites and other appropriate communication channels.

2. Michigan should regulate (with a “special purpose license”) all health care professionals regulated under Article 15 who provide health care services or consultation via telehealth across state lines to Michigan patients. Any health care delivered to Michigan residents across state lines through any technologically facilitated means shall be considered to be taking place in Michigan.. This legislation would be based on the Federation of State Medical Board’s Model Act to Regulate the Practice of Medicine across State Lines.
3. Because all telehealth across state lines to Michigan residents shall be considered to be delivered in Michigan, Section 333.16171(h) of the Public Health Code (which describes an exception for state licensure for health care providers from bordering states whose practice extends into Michigan, but who do not have an office or designated place to meet patients in Michigan) should be amended to indicate that regulated health care providers using Telehealth would not qualify for this exemption from Michigan licensure.
4. MDCH should include, by statute, a definition of E-health as part of the practice of medicine, and address the issues of the patient-provider relationship, confidentiality, and privacy. The statute should identify E-Health as being held to the same standards of all medical practice.
5. A “patient encounter” should be defined by statute to include any health care delivered by a health care provider to a patient through any technologically facilitated form of provider-patient communication. This statute should describe which, if any, health professions may engage in E-Health patient encounters through any means of technologically facilitated communication without first having an initial face-to-face encounter.
6. MDCH should communicate to private payers our recommendation that they formally recognize and reimburse for E-Health services provided by health care providers. The MDCH Medicaid Office should also consider formally recognizing and reimbursing for all eligible health care services provided through means of E-Health.
7. Licensing Boards should clearly communicate to their respective licensees the advantages, disadvantages, and risks of using E-health in the delivery health care. Boards should advocate that training in the appropriate use of E-health be part of a healthcare professional’s continuous professional development.
8. MDCH should identify the provision of E-Health as an important component of the emerging healthcare industry on their websites (such as the Michigan Healthcare Workforce Center, Health Careers, and Michigan Center for Health Professions websites), publications, and other sources of information for the public and healthcare professionals and encourage similar recognition of E-Health by the

Michigan Economic Development Corporation, Michigan Department of Labor and Economic Growth, and other appropriate state of departments.

9. MDCH should encourage all health professions to incorporate E-Health into the curriculum of all professional training programs, including the many privacy and ethical issues of such practices as email communication, provider-patient “blogs”, and professional practice websites.
10. An E-Health website should be created that provides both the public and health care professionals with important information, Michigan policies and relevant statutes, activities in other states, federal policies, resource documents, and other information regarding E-Health practices. This website should also contain information regarding the past, current, and future activities of any workgroup, task force, commission, or other official state body focused on E-Health.
11. Complete the E-prescribing recommendations regarding pharmacy administrative rules developed in 2001 (**Attachment J**).
12. The State Legislature and MDCH should amend existing statutes and enact new statutes that address the unfinished e-prescribing recommendations detailed in Table 1 of the 2001 Task Force on Internet Pharmacies Report (**Attachment J**).
13. The Michigan Legislature and MDCH should enact legislation that establishes the National Association of Boards of Pharmacy’s *Verified Internet Pharmacy Practice Sites (VIPPS)* standard for Internet pharmacies doing business in Michigan, as detailed in **Attachment J**.
14. The E-Health Workgroup should periodically reconvene to further explore and advise MDCH regarding a host of E-Health issues that may require new legislation, policy development, or staff action, such as the exploration of a state initiative to facilitate a statewide electronic health record, application for federal grants for E-Health pilot projects, the need for new E-Health legislation to help facilitate E-Health and protect the public, and addressing new technologies or new E-Health delivery issues.
15. MDCH should assure that state Medicaid policies are not a barrier to using E-Healthcare.

## I. BACKGROUND

The use of technology in the delivery of health care has increasingly become a recognized part of the health care industry dating back to the widespread use of telephones. Practitioner utilization of various electronic media to deliver information such as the internet, teleconferencing and computerized medical records is now becoming part of how we define “modern health care”. New technologies now afford health practitioners the ability to gather, store and disseminate vast amounts of patient data quickly and efficiently. With an ever increasing number of technologies available, it has become apparent to many state and federal health agencies that a review of presently available technology was required and that a coordinated plan for both the implementation and regulation of ongoing advancements is necessary. In the past ten years, there has been an accelerated investigation into technology-facilitated delivery of health care by professional associations, health professionals, and state and federal agencies. Both public and private health care entities have recognized the need to reach a consensus on terms and definitions and develop a more unified approach regarding the use of these technologies.

In September 2005, the Bureau of Health Professions convened a workgroup to examine the numerous issues related to the use of these technologies in the delivery of health care in Michigan. To ensure that proper regulation of the use of healthcare technology occurs, and to enhance patient care through an increased use of this technology, the workgroup was charged with the following tasks:

- Review the technologies currently utilized to gather, analyze, store and transmit patient health data.
- Review current federal and Michigan law affecting the use of technology in the provision of health care.
- Review the related positions, activities, and regulations of other states.
- Make recommendations to the Michigan Department of Community Health concerning changes and/or development of administrative rules or statutory law which would allow for increased utilization and proper regulation of technology when addressing health care data.

Between September 2005 and December 2006, the workgroup (**Attachment A**) met a total of four times (**Attachment B**). These meetings were structured to disseminate materials, build a working vocabulary of terms, identify and explore the issues related to health care technology, examine the benefits, risks and disadvantages of these emerging technologies, and develop recommendations for how our state should implement and regulate these practices.

## II. OVERVIEW OF TERMS AND CONCEPTS RELATED TO E-HEALTH

There is a growing interest in and implementation of what healthcare professionals frequently refer to as “*E-Health*”. Unfortunately, few agree on a clear definition of this term and the many terms and concepts related to E-health. A review of both the professional literature and policy statements and papers produced by private and public E-health offices reveals substantial differences in definitions of terms related to E-Health. Barely in use before 1999, the term “E-Health” now encompasses not only internet-facilitated medicine, but also virtually everything related to computers and health care. The term was first used by industry leaders and marketing people rather than academics. They created and used this term in line with other “e-words” such as *e-commerce* and *e-solutions*, in an attempt to convey the promises, principles, and excitement around e-commerce (computer-facilitated business) to the health arena, and to imply the new possibilities that the Internet is opening up in the area of health care. Intel, for example, referred to E-health as “a concerted effort undertaken by leaders in healthcare and hi-tech industries to fully harness the benefits available through convergence of the Internet and health care.” The Internet created both new opportunities and new challenges for health care information technology. Analogous to the promises of *e-commerce*, computers were seen to offer three new possibilities: (1) the capability of health providers to interact with their patients online (B2C, or the “business to consumer” of e-commerce); (2) improved capacity for provider to provider transmission of health care data and consultation (B2B, or the “business to business” of e-commerce); and (3) improved communication of health care information between patients (C2C, or the “consumer to consumer” of e-commerce). A form of C2C health care information is the practice of health care consumers using the World Wide Web to acquire information about countless numbers of health care issues from both professional and lay websites. Consumer use of online health information is now the norm, and most health consumers now report routinely looking up health information for themselves and other people. An estimated 82 million consumers used online health information in 2003. But the real number of individuals impacted by this information was more than 135 million people, as many users searched on behalf of others. Two-thirds of core Internet users report using the Web before or after consulting physicians or other health providers [5] [7].

E-health is often used to imply the universe of all forms of Internet-facilitated healthcare, ranging from the delivery of information, consultation and the availability of healthcare products to direct services offered by professionals, non-professionals, medical businesses or consumers themselves. But some believe even this definition is actually too limited. Gunther Eysenbach, one of the most frequently cited E-Health researchers [1], states:

*“E-Health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology. E-Health describes*

*the application of information and communications technologies across the whole range of functions that affect the health sector, from doctor to the hospital manager, via nurses, data processing specialists, social security administrators and- of course- the patients.”*

E-Health can encompass a wide array of services that are at the intersection of health care and information technology. Among the most “cutting edge” applications of E-Health include the following:

- The use of electronic medical records (EMR). The EMR term is a term currently used to indicate an historical record of patient care created and stored by the provider.
- The use of electronic health records (EHR). The EHR is the emerging notion of a health record co-created and shared by the patient, physician, insurers, laboratories and other parties of the health delivery system.
- Telemedicine, which is the delivery of health care at a distance.
- Evidence-based medicine, which are systems that allow health care providers to assess their treatment plans against a community, state or national database of effective treatment modalities.
- Consumer health informatics, which is the use of health information by health care consumers.
- Health knowledge management, which refers to a specialist’s database of best practices or epidemiological tracking of illnesses.
- Virtual healthcare teams, which refers to the sharing of digital sharing information and collaboration between health care professionals.

The terms *e-health* and *telehealth* are often inappropriately interchanged. E-Health is an umbrella term used to encompass all practices and issues related to the technologically-facilitated delivery of health care information, education, consultation, products and services. Although *telehealth* is sometimes used to describe both the delivery of remote care to a patient through technology and long distance health monitoring between a healthcare provider and a patient, it is most commonly used to describe health monitoring at a distance. There are two types of telehealth monitoring: phone monitoring (scheduled encounters via the telephone) and *telemonitoring* (collection and transmission of clinical data through electronic information processing technologies). Telehealth is often used to describe health monitoring in which the patient either actively (e.g., a patient performs a blood pressure monitoring at home and electronically transmits this reading to her health care provider 30 miles away) or passively (e.g., a patient continually wears a monitoring device which automatically transmits important health information to her physician’s office or hospital) enters information into some health monitoring system. In most cases of telemonitoring, an interactive monitor is placed in a patient’s home, often accompanied by measuring devices such as a blood pressure machine, weight scale, or pulse oximeter. This allows the patient’s current health status, symptoms, and activities to be monitored around the clock on a daily basis. So called “Quality Improvement Organizations (QIOs)” and other services are beginning to emerge which assist home health agencies, hospitals, and other health providers in implementing and utilizing telehealth as a tool to help reduce acute care hospitalization. Credible health



professionals, researchers and futurists are now predicting that within twenty years a “telehealthy home” will be embedded with wireless monitoring and care giving devices, such as 24-hour wireless monitoring of health and the use of robots that remind patients to take medications or monitor cognitive functions through interactive communication [2] [3].

Like the terms “medicine” and “healthcare”, *telemedicine* is often seen as a subset of telehealth used to describe the delivery of health care services at a distance. Here both clinical and non-clinical services (such as medical education, administration, consultation, assessment and research) are provided to patients or shared between providers. Telemedicine may be as simple as two health professionals discussing a case over the telephone or as complex as using satellite technology and video-conferencing equipment to conduct a real-time consultation between medical specialists in two different countries. It can also involve the use of an unmanned robot to provide health care information or services to a patient. Telemedicine generally refers to the use of any communications or information technologies for the delivery of clinical care.

Telemedicine holds the promise of electronically transporting the full range of medical care into remote areas. Patients seeking care or consultation who live hours or days from advanced or basic medical care can directly gain access to high quality medical expertise without leaving their community [4]. Telemedicine can be *synchronous*, or provided through “real time” video interactions, or *asynchronous*, provided through “store and forward” technology. Store and forward technology allows providers to transmit a patient’s health information for review by another provider at a later time. Real time *telemedicine* involving patient care may even be as complex as robotic surgery, which requires both patient and provider to be present at the same time with a communications link between them that allows real time interaction to take place. Videoconferencing equipment, peripheral devices attached to computers, and specialized robots may be used in such highly sophisticated applications of synchronous telemedicine. There are numerous applications of synchronous telemedicine that are beginning to be used across the country in such specialties as cardiology, gynecology, oncology, neurology, rehabilitation, internal medicine, obstetrics, psychology and psychiatry.

The focus of telemedicine has been largely asynchronous “store and forward” consultation between two health care providers, such as digital medical images and biosignals. This may involve a general practitioner consulting a specialist or two specialists consulting one another. This practice is becoming so common that the example of radiologists in India reading X-rays electronically sent from the U.S. was frequently cited in the 2000 U.S. presidential debate over “outsourcing”. Indeed, *teleradiology* is currently one of the major applications of telemedicine.

Another typically asynchronous form of telemedicine (although “instant-messaging” provides a potential opportunity for synchronous *telemedicine*), is *Cybermedicine*. This is the internet driven practice of medicine where patients and health care providers communicate via electronic email. Cybermedicine’s growth has led the American Medical Association (“AMA”) to scramble in order to keep up with the changes affecting

the healthcare industry. Many members of the AMA strongly oppose the growth of cybermedicine due to its potential negative effects on patient care such as the quality of care and the depersonalization of care especially as it relates to communication between the patient and the health care provider. Additional discussions on the potential effects of cybermedicine can be found on the AMA's website [6].

In spite of the concerns of the AMA regarding provider-patient cybermedicine, one manifestation of cybermedicine represents a major part of telemedicine: *e-prescribing*. The California Healthcare Foundation has defined *e-prescribing* as "entering a prescription for a medication into an automated data entry system (handheld, PC, or other), and thereby generating a prescription electronically, instead of on paper" [8]. Most healthcare policy experts agree that the important advantages of e-prescribing include 1) reduction of medical errors through more legible prescriptions; 2) keeping up with formulary changes from payers; 3) automated identification of alternative generic medications for cost savings; 4) automated warnings about patient drug interactions; 6) faster processing for patients at the pharmacy; and 7) improved capacity to track patient medication compliance [8]. E-prescribing promises to save billions of dollars and significantly improve patient safety. It is for these reasons that many states and federal agencies have either enacted legislation regarding e-prescribing or are advocating its use.

*Telenursing* is another term frequently part of a discussion of telehealth. Telenursing refers to the use of telecommunications technology by nurses to enhance patient care. It involves the use of electromagnetic channels (e.g. wire, radio and optical) to transmit voice, data and video communications signals. It is also defined as distance communications, using electrical or optical transmissions, between humans and/or computers. Telenursing applications are available in the home, hospital, through telenursing centers and through mobile units. Telephone triage and home care are the fastest growing applications today. The telephone on-call nursing services available at many pediatric offices across the country might be considered both a precursor to and another form of what we now refer to as telenursing.

The fact that E-health will be an important part of the future of medicine is becoming abundantly clear from a number of national and state developments. The United States HRSA had already established an Office for the Advancement of Telehealth as far back as 1989. Since 1989, the Office for the Advancement of Telehealth, formerly located with the Office of Rural Health Policy, has invested over \$250 million in funding telemedicine/telehealth demonstration and evaluation projects, including projects funded under the Rural Health Outreach Grant Program. The HRSA Office seeks to partner with states and private sector groups to create telehealth projects, provide technical assistance to groups regarding the implementation and assessment of telehealth programs and projects, promote knowledge exchange about best practices in this area, develop policies to improve access to quality health care services, and administer telehealth grant programs.

In 2004, President Bush created the Office of the National Coordinator for Health Information Technology in order to address interoperability issues related to creating a

National Health Information Network (NIHN) [9]. This network is essential for the establishment of a nationalized electronic health record (EHR). Privacy, interoperability, and the cost incurred in transforming all health records currently stored on paper are some of the major issues involved with a national EHR system. Once created, the NIHN promises to facilitate health care and save billions of dollars annually by allowing the capacity to share or transfer electronically stored medical records between health care providers, patients, hospitals, pharmacies, laboratories, and health insurance companies throughout the country.

A survey of U.S. hospital leaders between 2006 and 2007 revealed that a majority of hospitals have either a fully operational EHR system (32%), begun installation of such a system (37%), or have developed plans to build such a system in the near future (16%) [10]. Data from the National Ambulatory Care Survey, however, indicated that only 9.3% of U.S. physician's offices had a fully operational EHR system containing the four basic functions deemed minimally required for full operations: computerized orders for prescriptions, computerized orders for tests, automated test results, and physician notes. The Bush administration recently awarded six states federal grants to build a health information exchange system that will help the U.S. move toward a fully functioning national EHR system by 2014.

A number of noteworthy endeavors by state and federal agencies and private national organizations regarding E-Health further demonstrate the growing trend toward technologically facilitated health care delivery in the U.S. The U.S. Department of Defense adopted comprehensive telemedicine services in 1995, supporting ships at sea or soldiers in the field more than 8000 miles away from their medical centers in the U.S. in such varied areas as *telemental*, *telepathology*, and *teledermatology* [11]. In another federal effort, the U.S. Department of Veterans Affairs implemented the largest public telehealth patient monitoring systems in the country [2]. This \$20 million program remotely monitors the current 16,000 veterans served by the VA for a wide array of conditions. Early reports suggest a 30% reduction in medical costs for those patients who are monitored. The monitoring program is expected to expand to 90,000 veterans by 2009, with an \$18 million program pilot project to serve 13,000 veterans with telemental services for the burgeoning population of Iraq war veterans with post traumatic shock syndrome [12].

In addition to the offices established and E-Health policies developed by such major organizations as the Federation of State Medical Boards, American Medical Association, American Osteopathic Association, and numerous other state and national health care provider professional organizations, the Joint Commission has also addressed issues related to E-health for many years [16]. The Joint Commission is the nation's predominant standards-setting and accrediting body in health care. Early in 2004, the Commission organized a group of stakeholders to form the Professional and Technical Advisory Committee. This committee convened several in-person and teleconference meetings to specifically discuss proposed additions and changes to the Commission's 2004 Comprehensive Accreditation Manual for Ambulatory Care. It was an opportunity to get continued cooperative, interactive and representative effort between the *telehealth*

profession and private and public regulatory agencies. The group sought to mutually define the unique aspects of *telehealth* and establish guidelines in order to enhance the quality of the services that is provided to patients.

The Center for Telemedicine Law (CTL) was founded in 1995 by the Mayo Foundation, Cleveland Clinic, Midwest Rural Telemedicine Consortium, Texas Children's Hospital, and others and was then focused on overcoming barriers to the utilization of *telehealth* and related *e-health* services. The CTL became the Center for Telehealth and E-Health Law (CTeL) in 2000. It continues to be one of the leading national organizations known for briefing policy makers, analyzing complex legal, regulatory, and legislative information, providing testimony, writing comprehensive reports, and educating clinicians and industry leaders. It is also known for providing programming about how the expansion of telehealth and integration of health care technology can improve patient safety, reduce medical errors, and increase patient care access to primary and specialty care in both rural and urban settings [17]. The CTeL's many accomplishments range from working with the U.S. legislators to help get language regarding a \$10 million fund for telehealth into the FY 2006 Labor-HHS-Education Appropriations bill, to performing a 2005 analysis of whether skilled nursing facilities should serve as originating sites for telehealth as part of the Medicare Modernization Act. In 2003, under contract with HRSA's Office for the Advancement of Telehealth, CTeL wrote the often cited Telemedicine Licensure Report [18].

The National Governors Association Center for Best Practices recently announced the creation of the State Alliance for e-health, an initiative designed to improve the nation's health care system through the formation of a collaborative body that enables states to increase the efficiency and effectiveness of the health information technology (HIT) initiatives they develop [15]. The State Alliance will work with experts in the public and private sector to develop real-world HIT solutions and model practices. Estimates of potential savings from HIT adoption are substantial, as is the promise of better health outcomes and reductions in medical errors. States are poised to take a leadership role in removing barriers and supporting efforts for interoperable electronic health information exchange.

The State Alliance for e-health serves as a consensus-based state-level advisory and coordinating body that will enable states to:

- identify, assess and map ways to resolve state-level health IT issues that affect multiple states and pose challenges to interoperable electronic health information exchange;
- increase the efficiency and effectiveness of the health IT initiatives through collaboration;
- resolve privacy and security issues surrounding the use and disclosure of electronic health information; and
- learn from and leverage national efforts and resources to achieve interoperable health information exchange [15].

Tennessee Gov. Phil Bredensen and Vermont Gov. Jim Douglas are charged with overseeing consensus efforts to improve the nation's health care system through the effectiveness and efficient use of health information technology (HIT). The State Alliance met in Washington D.C. in January of 2007. Governor Douglas stated at the meeting that the goal is to provide health information to consumers and providers "any place, any time..." Governor Bredensen added that "If the e-health is to overcome the thorniest issues impeding widespread adoption, such as privacy and consumer protection, states have to be a partner." States now seem clearly poised to collaborate and partner in an effort to reap the benefits of health information technology.

Like most states across the country, numerous Michigan health care providers have been embarking on the implementation of some aspect of E-health at hospitals, public and private health clinics, and physician offices for over a decade. One of the first large-scale efforts of this kind was a nationally recognized E-health project in southeast Michigan. Detroit's Henry Ford Health System teamed with the Health Alliance Plan and a major innovator of *e-health portals* (Medseek) to implement two E-Health projects in 2005 [13] [14]. The first was an e-prescribing program engaging more than 300 primary care physicians and 577,000 patients in 24 medical centers, and is estimated to have avoided over 6,500 allergic reactions due to prescription errors or drug interactions and saved over \$3.1 million by increasing generic drug use in the first year of operation. Over 20,000 prescriptions were written weekly in this system. The second was an *e-Visit* system where virtual consultations between patients and their health care providers can take place. Over 100,000 enrolled patients were able to go online and obtain lab results, view customized health information, renew prescriptions, and describe their non-urgent health concerns to caregivers and receive instructions for treatment and/or scheduling a follow up medical visit. The system promises to increase patient safety and patient satisfaction, and greatly improve the quality of health care. Other hospitals, universities and medical centers in Michigan are also investing millions of private and public dollars into a diverse number of major E-Health initiatives, such as a telehealth collaborative among six rural hospitals in southwest Michigan [29] and the effective implementation of telemedicine fourteen hospitals through Michigan's Upper Peninsula Healthcare Network [30]. These efforts, along with such state resources as the University of Michigan's new Center for Information Technology [31] and Michigan Department of Community Health's nationally recognized Health Information Exchange Initiative [32] indicate our state's advancement toward an E-health future.

### III. ISSUES RELATED TO IMPLEMENTATION OF E-HEALTH

In an article describing both the promise and the complexity of E-Health, a prominent author recently suggested there are "ten e's" of E-Health [1]. It was suggested that E-Health will:

- increase the *efficiency* and *enhance* the quality of health care
- both benefit from and contribute to *evidence*-based health care
- *empower* consumers with both knowledge bases of medicine as well as accessible personal electronic health records

- *encourage* a new more egalitarian relationship between patient and provider
- *educate* health providers with online continuing medical education and accessible consultation, and *educate* health consumers with vast amounts of health information and easy access to second opinions
- *enable* information exchange and communication in a standardized way between numerous health care establishments
- *extend* the scope of health care beyond its current conventional boundaries
- create new *ethical* challenges and threats to health care delivery, such as the ethical issues connected to online professional practice, informed consent, and privacy
- will make health care access more *equitable* for some (such as rural patients separated from major medical centers) and less equitable for others (such as those without the money, skills or access to computers or computer networks). Indeed, some of the people who could benefit most from long distance care (the poor, isolated, and medically indigent) are those least likely to have the capacity or resources to use the technology.

Many health professionals predict that the growth of E-health over the next 20 years will have as powerful an impact on health care in the 21<sup>st</sup> century that the advent of antibiotics or vaccines did in the 20<sup>th</sup> century [3]. This is thought to be especially true when considering the simultaneous breakthroughs that are now expected from the research related to stem cell developments and the human genome project. But as we move toward this apparently inevitable paradigm shift in the healthcare industry, there are a number of ideological, technological, political, regulatory and ethical issues that represent challenges for the healthcare industry. Before considering what other states are doing to adopt E-health practices and policies, and before considering what Michigan's E-health workgroup accomplished and recommended, a brief review of the major issues of E-Health will be briefly identified. These issues represent some of the most important issues discussed at by the E-Health Workgroup.

#### A. The Provider-Patient Relationship and "Duty of Care" in E-Health

The E-health policy literature is replete with concern about both defining and protecting the provider-patient relationship. Traditionally, for a doctor-patient relationship to exist there must be a sort of contract, expressed or implied, between the doctor and the patient. This relationship is usually described as an agreement that is solidified when the doctor agrees to give medical treatment and when the patient accepts the physician's medical services. Nevertheless, the lines become unclear in telemedicine and cybermedicine, when determining whether a doctor-patient relationship can exist online or through email. A number of online medical providers accept the patient's description of their illness or medical problem, and are willing to treat them accordingly. Others require a description of the symptoms to be reported by the patients existing medical provider. For instance, many online doctors will not fill a prescription without a referral from another physician who has seen the patient. Of greatest concern is the growing number of primarily medical and mental health professionals that are willing to provide advice, consultation, and even treatment to any patient with the means to pay for it. The question for many

policy experts and practitioners is “When does the provider-patient relationship begin, and what safeguards must exist in non-face-to-face encounters in order to assure that the quality and confidentiality of health care is not compromised?”

Another important issue related to the provider-patient relationship in E-health is the so called “duty of care”. In general, duty of care refers to the duty to do everything reasonably practicable to protect others from harm. In the delivery of health care through non-face-to-face encounters, this would include doing everything reasonably practical to provide confidential, high quality health care and assuring that the patient has access to quality follow up care. The E-health provider breaches his or her duty of care when he or she fails to perform in the same manner that a reasonably prudent physician would perform face-to-face. In cybermedicine and telemedicine, that standard has not been legally determined because a major medical malpractice case has not yet been brought against such a provider. The legal standard for duty of care is bound to be different for E-health encounters than face-to-face encounters, the question becomes how will the standard be stricter- or perhaps somewhat more relaxed- in order to safely accommodate this health care delivery model.

Written and verbal (face-to-face and telephone) communication have traditionally been the primary mechanisms for communicating health information. However, with advances in technology, Internet applications for communications among physicians and between physician and patients are emerging as another viable avenue for patient communication. E-mail communication is especially useful for information the patient or the provider wishes to or needs to commit in writing. E-mail messages can also embed links to educational materials and other resources on the practice’s Web site or to external sites. In some electronic mail applications, clicking on a “live” universal resource locator (URL) link inside a mail message launches a web browser and takes the user directly to the indicated resource. Practices can provide lists of URLs on a particular topic- such as pregnancy, cholesterol control, or managing high blood pressure- and create e-mail reply templates with pointers to frequently used sites. One duty a provider has when referring patients to online health information websites is to assure that these sites are both useful and professionally credible. Referral to unseemly or misleading information could violate the medical tenant of “do no harm” as significantly as failing to use antiseptic procedures [7].

There are a number of professional associations that have offered guidelines regarding long distance communication between provider and patient. Some of these guidelines address email communication, online communication, and various other synchronous and asynchronous communication technologies. One such set of guidelines is the American Medical Association’s (AMA) *Guidelines for Physician-Patient Electronic Communications (Attachment C)*. These guidelines, which focus on e-mail communication between a patient and provider, hold that electronic communication between a provider and patient must never replace the crucial interpersonal contact that is the very basis of this very important relationship. This technology should only augment the face-to-face relationship. Although these guidelines do not thoroughly address all of the issues related to privacy, security, and ethical standards, they are particularly useful

for practices that wish to establish guidelines around the many technical, legal, professional and administrative components of an e-mail system for communication of confidential health care information.

An important source of guidelines for online communication can be found from Medem, a collaboration of over a dozen of the nation's medical societies and 30 malpractice carriers representing over 70% of the nation's insured physicians. Medem established an *eRisk Working Group for Healthcare's Guidelines for Online Communication* in 2000 to address the issues and concerns associated with physician-patient interaction and communication via the Internet and World Wide Web (**Attachment D**).

The eRisk Working Group guidelines document is a "living document" that is frequently updated with important revisions regarding new considerations or new technologies.

The eRisk group identifies ten general principles addressing the implementation of communication related to email, web sites, Internet, list serves, electronic health records and other electronic services and communication. A summary definition of each of these principles is shown below:

1. *Confidentiality*. Assuring the patient privacy required by HIPAA specifications for online communication is described, including written statements indicating this communication may not be secure. Standards for privacy, security, and authentication are described.
2. *Unauthorized Access to Computers*. Guarding against unauthorized use by inappropriate staff and those with access to the patients computer is addressed, including automatic logout and password protection.
3. *Informed Consent*. Documented (and signed) patient consent to communicate with the provider online should be obtained and kept in the permanent medical record of the patient. This consent should include agreeing to appropriate use of online communication and other specified protocols.
4. *Pre-Existing Clinical Relationship*. It is recommended that all online communication with a patient occur only after a face-to-face evaluation in the office setting.
5. *Licensing Jurisdiction*. Providers who provide medical consultation to a patient from another state must hold a license to practice medicine in the state where the presenting patient resides. Consultation between two providers from different states does not require in-state licensure, provided that such consultation is referenced in a report they issue.
6. *Sensitive Subject Matter*. Clinicians should advise patients that sensitive issues (such as mental illness, sexual history, substance abuse, genetic disorders and HIV infection) may not be safe to communicate online, due to the ability of unauthorized individuals or law enforcement to access these records. It may be advised to either ban such topics or acquire patient consent before discussing such subjects online.



7. *Patient Education and Care Management.* Any educational information or websites the provider refers the patient to should either be directly from the provider's practice or come from a credible, authoritative source.

8. *Emergency Subject Matter.* Patients should be advised to not use online communication for matters that are of an emergency nature (such as chest pains, excessive bleeding, or high temperature).

9. *Medical Records.* A permanent record of all online communication between patient and provider as well as between the provider and other providers should be kept as part of a permanent record (either electronically or on paper).

10. *Practice Web Site Communications.* All patient information on a Practice Web Site should be professional, authoritative information. Commercial information, particularly in such areas as cosmetic procedures and off-label drug use, is discouraged. A disclaimer page should be used to advise patients when they are leaving the practice site to other web sites.

These guidelines highlight several areas addressed by many prominent policy experts and professional associations. The eRisk group also addresses fee-based online consultations between patient and provider with seven guidelines that reflect issues that are discussed in the ongoing national dialogue regarding online communication:

1. *Informed Consent.* All such online communication should be preceded by recognized and accepted terms of agreement by the patient and provider.

2. *Fee disclosure.* All fees must be disclosed, with recognition that insurance may not cover some fees.

3. *Identity Disclosure.* The clinician should make his/her identity clear to the patient.

4. *Available Information.* The provider should specify in the *terms of agreement to communicate online* that the services rendered are based only on what information is available through this mode of communication- that there may be limits to a consultation that is not face-to-face.

5. *Online Consultation Versus Online Diagnosis and Treatment.* Online consultation is appropriate for a known (previously diagnosed), pre-existing condition. Diagnosis and treatment of conditions online may compromise patient safety and increase liability exposure. If diagnosing a condition online, communicating the importance of a follow up office visit or referral to another practitioner is required.

6. *Follow Up Plans.* All online consultations should contain an explicit follow up plan, as clinically indicated, which is clearly communicated to the patient.

*7 Internet Pharmacies.* The use of Internet pharmacies should be discouraged, unless the pharmacy has the VIPPS (Verified Internet Pharmacy Practice) seal of approval. Some of these pharmacies may dispense drugs without a valid doctor's order, be involved with illegal drug importation, or represent illegal "offshore" operations unencumbered by FDA or DEA regulations.

Another set of guidelines of the eRisk Group contain 11 recommendations for the implementation of a Personal Health Record (PHR). The PHR is similar to what has been called the Electronic Health Record (EHR), in that it is a medical record that the patient has access to and can provide input to. The PHR, however, is owned and maintained by the patient, with providers and other health care entities able to enter and retrieve information from it. The PHR is sometimes offered as a service by the provider as a portal for patient-provider communication and repository of relevant health information the patient inputs. The 11 recommendations define the use and value of such systems and offer guidelines for implementation.

A third major source of guidelines for the use of the Internet in the delivery of health care is the Federation of State Medical Board's (FSMB) *Model Guidelines for the Appropriate Use of the Internet in Medical Practice (Attachment E)*. These guidelines are written in the form of a model policy that a state Board (medical or other appropriate profession) could adopt as an official recommendation. Like the eRisk Group guidelines, the FSMB guidelines address some of the critical issues of the patient-provider relationship that must be considered in order to properly implement this technology in medical practice. The five sections of the FSMB guidelines provide a model statement that 1) introduces the potential benefits and necessary safeguards of online communication between patient and provider, 2) identifies the overarching ethical standards of Internet communication, including candor, privacy, integrity, informed consent, and accountability, 3) describes the importance of the provider-patient relationship, 4) defines the terminology related to the patient-provider relationship, including *medical practice site*, *general health information site*, *personal health information*, *physician-patient e-mail*, *passive tracking mechanism*, and *web site*, and 5) specifically defines and prescribes guidelines for the implementation of internet communication in medical practice, addressing such salient topics as treatment, electronic communications, informed consent, medical records, compliance with state and federal laws and web standards, disclosure, accountability, advertising and/or promotion of goods and services, and the use of external links.

The FSMB Model Guidelines encapsulate the ethical issues often raised in the context of E-health and the patient-provider relationship. Because the internet eliminates the important interpersonal cues and information we obtain from face-to-face encounters and utilizes communication technology that is vulnerable to unwanted interception, the values of candor and integrity are paramount. Only through precautions to protect privacy, assure accountability, and implement informed consent can a provider protect the safety of the patient and confidently provide health care in an atmosphere of trust and personal engagement.

## B. Patient Safety and E-Health

As discussed above, patient safety is both a concern and a benefit of E-Health. Providers must assure patient safety while transferring communication and health care data electronically. But as the description of e-prescribing above suggests, patient safety can actually improve through the use of computer technology. By reducing prescription errors and avoiding deleterious drug interactions, e-prescribing saves lives.

Patient safety is critical to high quality health care, and is the foundation of the Hippocratic Oath of first “doing no harm”. Patient safety is a major impetus behind the regulation of health care professionals in every state. In its purest form, it demands perfect information, perfect processes, and perfect clinical decisions across the spectrum of patient care. Although perfection is unrealistic, patient safety can be improved by removing its main obstacle – medical errors. Patient safety is about more than just medical error prevention; it is also about sound treatment planning, clinical excellence, proper diagnoses, correct processes and procedures, and appropriate patient therapies.

Numerous public and private policy centers, think tanks, and professional advocacy organizations have linked E-health to improving patient safety, particularly by reducing prescription errors and improving continuous access to health care. The U.S. Health and Human Services/Office of Health Information Technology [19] identifies the reduction of medical errors and the improvement of quality health care- both related to improvements in patient safety- as two of the six benefits it identifies with health information technology. It is for this reason that many states have moved relatively quickly toward supporting policies and legislation to facilitate e-prescribing, compared to other aspects of E-health use and regulation.

## C. E-Prescribing

Simply defined, e-prescribing is the use of an automated data entry system to generate a prescription, rather than writing it on paper. Forty-six (46) percent of Americans use at least one prescription medication daily. In 2001, 3.1 billion prescriptions were written at a cost of \$132 billion. This cost is expected to reach \$414 billion by 2014. In addition, there are tremendous costs related to the 2.1 million adverse drug events each year causing 190,000 hospitalizations and thousands of deaths [28]. The benefits of e-prescribing and its association with enhanced efficiency, patient safety, patient satisfaction, medication compliance, and formulary adherence are widely accepted in the healthcare community. But there are also significant cost savings to both patients and providers as well. Patients save through automated identification of generic alternative medications and avoidance of costly medical treatment due to prescription errors or drug interactions. Providers save by decreasing vulnerability to medical malpractice due to prescription errors. Providers also save by spending less time communicating with pharmacists clarifying prescriptions. One estimate suggests that pharmacists make 150 million telephone calls to physician offices [27] per year. In this time of spiraling health care costs, e-prescribing is one E-Health application that has increased exponentially among both private medical practices and hospitals. But as discussed previously, there

are also numerous concerns related to this asynchronous E-Health application, including privacy and security issues and the growing number of unregulated and/or unscrupulous e-pharmacies.

As of 2007, there are 9 states in the U.S. that have enacted statutes that specifically address and facilitate e-prescribing: Delaware, Florida, Idaho, Illinois, Maryland, Michigan, Montana, Tennessee, and Washington (**Attachment I**). Several other states have enacted legislation to evaluate this E-Health application, define what it is, or regulate some component of e-prescribing. This is one aspect of E-Health that that distinguishes Michigan. In early 2006, Michigan was recognized for its commitment to improving patient safety and efficiency in the drug prescription process with its use of electronic prescribing technology. This annual *SafeRx Award* placed Michigan as 10<sup>th</sup> in the nation for the number of prescriptions routed electronically over the *Surescripts Electronic Network* in 2005. In early 2007, Michigan's national ranking moved from 10<sup>th</sup> to 6<sup>th</sup> in the nation for electronic prescriptions. Greatly contributing to Michigan's high rate of e-prescribing are several nationally recognized efforts involving collaborative projects in the state between major Michigan health system's, employers, and health insurance organizations. In addition to Michigan's private e-prescribing projects that have developed in recent years, there has also been a keen interest in e-prescribing in the public sector. In January of 2000, the Michigan Department of Consumer & Industry Services convened a task force to examine issues associated with the practice of prescribing and dispensing medication over the internet. In June of 2001, the *Report on Task Force on Internet Pharmacies and Prescribing* was published (**Attachment J**). The Report examined the issues of e-prescribing and made several recommendations designed to facilitate and regulate the proper use of e-prescribing as well as protect the public from unscrupulous e-pharmacies. A brief summary of the recommendations include the following:

- 1) *Amend the definitions of dispensing, pharmacy, prescriber, prescription, and substitution to reflect the impact of Internet pharmacy practices.*
- 2) *Define the nature of the prescriber-patient relationship, require verification of the prescription's validity, the identity of the patient, and the identity of the provider.*
- 3) *Adopt standards such as the Verified Internet Pharmacy Practice Site (VIPPS) criteria for identifying a legitimate Internet pharmacy.*
- 4) *Eliminate the current restriction on mail order pharmacies.*
- 5) *Establish licensure requirements for Internet and mail order pharmacies.*
- 6) *Provide requirements to assure confidentiality via the Internet.*

As a result of these recommendations, a number of administrative rule changes were drafted for incorporating into the Pharmacy General Rules. These rule changes were all recently completed. The draft rules are shown in **Attachment K**. Another result of the

work of this task force was to create the impetus for the formation of the E-Health Workgroup to further examine E-Health in a broader context. The Workgroup discussed the importance of the 2001 task force recommendations, and recognized there were still several recommendations that had not been implemented that were critical to the safe, statewide implementation of e-prescribing. Thus, some of the recommendations of the E-Health Workgroup will be to complete some of the unfinished recommendations of the 2001 task force recommendations related to e-prescribing.

#### D. Regulatory Issues of E-Health

There are a number of potential regulatory issues related to implementing E-Health. Health care professionals are regulated by states. Statutes and administrative rules describing how these statutes are implemented dictate the legal practice of medicine, nursing, psychology, or any other regulated health profession. Existing state laws across the U.S. that regulate E-Health, such as the interstate practice of *telemedicine* or the increase in consumer-provider or provider-provider consultations via the internet, have not kept pace with the growing use of such practices by health professionals. As partially discussed above, some of the major regulatory issues are:

- privacy
- confidentiality
- parental rights
- quality of service
- jurisdiction
- standards of practice

A major focus of much attention regarding E-health by states in the past several years has been regulating the increasing amount of the interstate practice of medicine through E-health. The HRSA Office for the Advancement of Telehealth has identified licensure as a major barrier to the development of telemedicine in the U.S. [20]. Proposed practice models have presented challenges to both providers and regulators. Health care providers are justifiably concerned about engaging in practice in states in which they do not hold a license and thus do not have clear legal authority. Regulators are uncertain regarding their ability to control and sanction the quality of care rendered to in-state residents by out-of-state providers. The HRSA Office for the Advancement of Telehealth has identified eight licensure models that address cross-state licensure issues in some fashion. In summary, those eight models are:

1. *Consulting Exceptions.* A physician who is unlicensed in a particular state can practice medicine in that state at the request of and in consultation with the referring physician. Some consulting exceptions permit a specific number or percentage of practice per year.
2. *Endorsement.* State boards can grant licenses to health professionals in other states that have equivalent requirements.
3. *Reciprocity.* Authorities in each state agree to recognize licenses issued by the other state without further review of individual credentials.

4. *Mutual recognition.* Licensing authorities voluntarily agree to legally accept the policies and licensure processes of a licensee's home state. The nurse licensure compact is based on this model. After thoughtful consideration, Michigan rejected the option of entering the nurse licensure compact in 2006 based on regulatory concerns.

5. *Registration.* A health professional licensed in one state would inform authorities of other states that s/he wished to practice part time there. S/he would agree to operate under the legal authority and jurisdiction of the other state, and would be held accountable for breaches in any state they are registered in.

6. *Limited Licensure.* A health professional would have to obtain a license from each state in which s/he practiced but would have the option of obtaining a limited license for the delivery of specific services under particular circumstances. This system would thus limit the scope rather than the time period of practice. The FSMB has proposed a variation of this model (described below).

7. *National Licensure.* A national licensure system could be adopted on the state or national level. A license would be issued based on universal standards of practice for a given profession in the U.S. If administered at the national level, issues related to state revenue loss, legal authority, and data management would make this option unlikely to ever be adopted. If administered at the state level, the issues would be less daunting, but states would still have the formidable task of agreeing on a set of universal standards regarding both qualifications and discipline.

8. *Federal Licensure.* Under a federalized system, professionals would be issued one license, valid throughout the U.S., by the Federal government. Even the relatively few strong advocates for this system acknowledge that states would still have to play a major role in implementing such a system.

Although a number of health professions are studying the issues, medicine and nursing are currently taking the lead. Both of these professions have adopted formal approaches to adapting state licensure requirements to accommodate practice across state lines. Over the past 50 years, the basic standards for medical and nursing licensure have become largely uniform in all states. Physicians and nurses must graduate from a nationally approved educational program and pass a national medical or nursing licensure examination. Every state must "endorse" individual candidates moving from other states. However, there are significant differences in the administrative requirements and filing fees, which can pose as barriers to physicians and other health providers attempting to establish a multi-state practice. For physicians, these exceptions can sometimes be overcome through "consultation exceptions" which allow occasional, infrequent, or limited practice within a state.

While endorsement is currently the most common method used by state regulators to recognize an individual licensed by another state, the practicality and efficiency of this option are being tested by the multi-state nature of the expanding E-health practice. While endorsement works adequately for a practitioner who moves from one state to

another, there are still significant delays and duplications in the process. These problems are compounded for multi-state telehealth practitioners. They must apply for a license in each state where practice occurs, and are subject to additional and varied continuing education and other practice requirements. In an effort to create an efficient system that would allow for professional practice in multiple states, medical and nursing regulators have approached licensure revision in different ways.

With respect to medicine, most state medical boards have taken the position that practice of medicine occurs in the state where the patient is located. State medical boards take seriously their responsibility to protect the public. They want regulatory control over any physician treating patients in their state, even if the physician never enters the patient's state and is already licensed by another state. In 1996, the Federation of State Medical Boards endorsed model legislation (*A Model Act to Regulate the Practice of Medicine Across State Lines*) that would create a "special-purpose license" to practice medicine across state lines for a doctor holding a full and unrestricted license to practice medicine in any state (**Attachment F**). This model was designed to allow states to appropriately provide regulatory control over physicians not physically practicing within a state's jurisdiction. The FSMB specifically declined to endorse a model that would have created a single, nationwide license to practice telemedicine due to the complexity and untenable prospects of creating a national licensure system.

Eight states have adopted legislation for a "special purpose" license based on the Model Act: Alabama, Colorado, Minnesota, Montana, New Mexico, Ohio (certificate), Oregon, Tennessee and Texas. Nineteen (19) states do not have any statutes regarding license requirements which address telehealth, which includes New York, Wisconsin, and Michigan. Twenty-one (21) states require a full license by statute to provide telehealth in their state from providers from other states, which includes California, Mississippi, and Florida. Three (3) states have issued policies or regulatory statements requiring a full license to provide telehealth in their state, which includes Kansas, Louisiana, and Wyoming. Washington has developed statutory language that implies that providers with full licensure have permission to provide telehealth in that state.

Professions other than medicine and nursing also face similar and unique professional and regulatory issues regarding telehealth and other practice across state lines, although few of these professions have addressed these issues in state legislation. Health professional boards and professional associations in such fields as mental and behavioral health, speech-language-hearing, teledentistry, occupational therapy, pathology, and dietetics are currently engaged in discussions about whether licensure changes should be made to accommodate telepractice. Though several of these groups have engaged in some isolated efforts to advocate for telepractice friendly legislation, there are currently no broad trends that can be identified. In 1994, the American College of Radiology adopted a "Standard for Teleradiology" and developed a Model Act based on the endorsement model. That same year, the American Medical Association adopted a policy that "states and their medical boards should require a full and unrestricted license for all physicians practicing telemedicine within a state." The College of American Pathologists

model is a variation of the endorsement model, and requires a physician to have their license endorsed in each state from which they receive patient specimens or information.

A particularly interesting and important development in E-health is related to the numerous mental and behavioral health fields, such as psychiatry, clinical psychology, counseling, and social work. A wide range of E-health applications have rapidly emerged in the past 15 years [21]. The general public and mental health sufferers can join large online educational and support communities to share personal information with a depth unprecedented in the face-to-face world. Countless support groups and professional advocacy organizations host online services providing education, referral, provider location information, chat opportunities, Q & A, informal consultation, and other online services in such areas as depression, ADHD, divorce, drug and alcohol addiction, phobias, and almost every type of mental disorder or life circumstance known. Numerous Email clinician practices (both single and group practices) have formed which offer brief responses to short questions from the public. Two well known practices- *Shrink-Link* and *Help-Net*- have been widely criticized [23]. These practices typically present themselves as advisers, rather than offering therapy. However, critics contend they are providing a form of therapy that potentially involves a long-term relationship with a therapist, but do not adhere to APA and other mental health professional standards regarding the proper maintenance of a therapist-patient relationship, confidentiality, proper assessment and follow up and overall protection of the client's interests.

Most trends in E-Health among mental health providers have a great potential for improving mental health care in the U.S. Many hospitals, HMO organizations, mental health clinics, and therapy practices have implemented telemonitoring devices and online information services for depression patients and other mental illness sufferers in order to support self-help, prevent suicide, and avoid re-hospitalization. Another telehealth trend is the interest many practitioners are beginning to take in the potential for long-distance therapy. After 2000, Internet-based technologies began to converge with satellite and cable television on a widespread basis, making way for fully interactive broadcast capabilities delivered through one, seamless technology. Today, it is now believed by many mental health policy experts that E-health will increasingly facilitate more and more interactive mental health services between therapists and their patients. Thus, the "virtual office" will become an integral part of the future of psychology practice, including routine online video-therapy, or *telemental*, between practitioner and patient via computer, cell phone, or some other future technology

As in medicine and nursing, the use of the internet by mental health practitioners to provide mental health care is increasing at a much greater pace than legal and ethical adaptations can be made. The American Psychological Association issued the "APA Statement on Services by Telephone, Teleconferencing, and Internet" in 1997, which essentially postponed a revision of the APA Ethics Code regarding the use of telephone, teleconferencing, and the internet to some (as yet unattained) future date. The statement simply deferred to previously issued general APA standards that recommend a psychologist 1) take reasonable steps to protect patients, clients, research recipients from harm, 2) obtain informed consent, 3) assure confidentiality, 4) honor patient boundaries,



5) avoid harm, 6) describe the nature and expected results of therapeutic intervention, and 7) follow standards for proper advertising [22]. In addition, the National Board for Certified Counselors (NBCC) in 2000 promulgated brief statements on Internet-related ethics. This set of policy statements addresses the definition and types of technology-assisted counseling, standards for ethical practice of internet counseling, and the issues of confidentiality, licensure, and certification (**Attachment G**). Although these statements are a useful attempt to define the terms of E-health for counselors and address some of the regulatory and technical issues, they do little more than offer broad definitions of internet counseling and reiterate the importance of adhering to standards for face-to-face counseling. The technical, regulatory and financial issues of providing mental health services through E-Health, as in medicine and other professions, are on the precipice of being formed. Currently, most mental health policy experts and professional bodies agree with the National Board for Certified Counselor's statement that:

*Policies of membership organizations, professional certifying bodies, and state or provincial licensing boards need to be reviewed. Also, as varying state rules and opinions exist on questions pertaining to whether Internet counseling takes place in the Internet counselor's location or the Internet client's location, it is important to review codes in the counselor's home jurisdiction as well as the client's. Internet counselors should also consider carefully the local customs regarding age of consent and child abuse reporting, and liability insurance policies need to be reviewed to determine if the practice of Internet counseling is a covered activity.*

#### E. Reimbursement Issues

In addition to provider perceptions, licensure, regulation, data standards, privacy and standardized definitions, reimbursement issue are often identified among the major impediments to the implementation of E-health across the U.S. Even though extensive research documents that telemedicine is a feasible and cost effective alternative to traditional health care [24], universal reimbursement for telemedicine has been ignored by both public and private payers. A brief history of reimbursement for telemedicine is instructive [25].

Effective 1999, the Balanced Budget Act of 1997 was the first piece of federal legislation to mandate that Medicare must reimburse for telemedicine services. However, numerous unrealistic constraints resulted in a drastic reduction of reimbursement below that which was originally predicted. These constraints included limiting reimbursement to only rural health professional shortage areas and only specific CPT codes, excluding store and forward telemedicine services, requiring a 75%/25% fee split between teleconsulting physician and referring practitioner, and excluding registered nurses from the presenter list. The Centers for Medicare & Medicaid Services (CMS) had predicted between \$60 million and \$690 million would be reimbursed to telemedicine providers in 1999. Instead, only \$20 million was reimbursed for telemedicine encounters.

In 2000, Congress passed the Benefits Improvement and Protection Act of 2001. This act abolished the fee splitting requirement in favor of a \$20 origination facility fee,

eliminated presenter requirements, expanded eligible CPT codes, expanded geographic locations, and permitted reimbursement for store and forward services in federal demonstration projects in the geographically isolated states of Alaska and Hawaii. These changes did result in increased federal reimbursement for telemedicine. However, of the 34 states now receiving Medicare reimbursement for telemedicine, Michigan is not among them. Furthermore, there are 21 states in the country that have enacted state telemedicine and telehealth reimbursement laws (13 states) or have enacted legislation impacting reimbursement for telemedicine and telehealth (8 states), including such states as California, Minnesota, Texas, Arizona, New Mexico, Oregon, and New York. Michigan is one of the 29 states that have not enacted any legislation regarding reimbursement of E-health services.

While the majority of legislative activity surrounding telemedicine reimbursement deals with public funding, there is a significant amount of interest and legislative activity in states regarding private payers. Currently, five states (California, Texas, Oklahoma, Kentucky and Louisiana) have specific legislation regarding private payer reimbursement for telemedicine, and countless providers from other states are receiving reimbursement for telemedicine services across the country [24]. In fact, in 2003 a survey indicated that there are 38 telemedicine programs in 25 states that receive reimbursement from over 100 private payers. One such program previously discussed, Henry Ford Health System's e-prescribing and online medical visit, is an example of such a program with private payer collaboration, including Blue Cross/Blue Shield [13] [14]. Many private payers are looking to Blue Cross/Blue Shield for leadership, as they are reimbursing for telemedicine in 21 states (versus Medicaid, which now reimburses in only 18 states).

Because private payers account for over half of the total national expenditures on healthcare and almost 70% of U.S. citizens are covered by private health insurers, private payer coverage is thought by many to be necessary to drive the continued development and implementation of telemedicine programs and services. An example of a state statute regarding the reimbursement of telemedicine services by private payers is the Texas law requiring such reimbursement (**Attachment H**). In a recent 2005 survey of healthcare organizations providing potentially billable telemedicine services, 55% indicate they are currently receiving reimbursement for telemedicine from private payers. Of these 55%, 44% were affiliated with academic programs, 47% were nonprofit organizations, with the remaining 9% including such entities as a state agency and a private managed care organization. These survey respondents indicated that approximately 130 private payers were being billed for approximately 75 clinical specialties. In most of these claims (81%), there was no difference between the amount of reimbursement for these services and the amount the provider would have received for the same service face-to-face. It is essential that healthcare organizations begin billing private payers for services delivered through E-Health, since so many states cannot currently rely on Medicaid reimbursement for such services.

#### IV. LEGISLATIVE ACTIVITY IN OTHER STATES

Different aspects of legislation regarding E-Health services in other states has been discussed throughout Section II of this paper. Between 2005 and 2007, a flurry of laws have been enacted or at least proposed in almost every state impacting the delivery of health care via E-Health. This is especially true if one considers legislation from such varied issues as the nurse compact, e-prescribing, and health information exchange [26]. One-hundred and twenty-one (121) bills were introduced in 38 states in the past two years dealing with some component E-Health. Thirty-six (36) bills were passed in 24 states during this period calling for the use of health information technology to improve healthcare, and ten (10) state governors have passed executive orders related to health information exchange. Fifty-three (53) bills were introduced in 25 states, and 19 bills were passed in 13 states, calling for the creation of a commission, committee, task force, or council to provide leadership or recommendations on E-Health and/or interstate health information exchange. A great deal of this legislative activity is driven by national policy trends or federal initiatives. For instance, the previous reference to President Bush's Executive Order of 2004 to promote quality and efficient delivery of healthcare through the use of health information technology that is transparent, accessible and interoperable between states by 2014 is the incentive for many states with an interest in creating such a system.

This is a salient moment for the advancement of state legislation that recognizes the importance and implementation of E-Health in Michigan. States like Michigan are facing many challenges today related to healthcare, including tightening budgets, the need for economic development, rising energy and healthcare costs, educational challenges, decreasing Medicaid reimbursement, health care shortages, and emergency preparedness in the age of terrorism. State leaders increasingly recognize that E-Health may help to address many of these challenges. In January of 2007, governors, state officials, federal bureaucrats and health experts met for the inaugural meeting of the State Alliance for e-Health. This was an initiative of the National Governor's Association's Center for Best Practices. The charge of the state alliance is to advance the adoption of health information technology and interoperable health information exchange. This system of health information exchange is not likely to become a uniform, federalized health information system. However, states are taking seriously the coordinated effort to create an electronic health record system that transforms healthcare delivery and contains the burgeoning costs of health care. Although states recognize the high initial cost of such a system, it is also recognized that without such a system the future costs of healthcare will be unmanageable. As reflected by increasing state and federal legislation, creation of new state commissions, new federal funding for numerous E-Health pilot projects, and the state, federal and private policy offices focusing on E-Health, it is clear this is a pivotal point at which the Michigan Department of Community Health must be prepared to advance appropriate policies and enact necessary legislation to help foster what appears to be a technological transformation of health care delivery in the U. S.

## V. WORKGROUP ACTIVITIES AND DISCUSSION

Between 2005 and 2007, the Bureau of Health Profession's E-Health workgroup met a total of five times (September 2005, November 2005, May 2006, December 2006, and October, 2007). **Attachment B** contains meeting agendas, minutes, and other relevant notes from these five meetings of the Workgroup.

The first meeting of the workgroup explored the important concepts and issues related to E-Health. This group discussion explored the definition of E-Health, the benefits and risks, and the important issues the group wanted addressed in the final report. This meeting helped the workgroup members define the concepts and issues of importance, and express individual priorities and concerns.

The second meeting explored the project outline, examined and discussed informative handouts and reference documents, and explored strategies for group discussions. This discussion established a relatively short timeframe of meetings to thoroughly identify the issues, shape the direction of the project, and complete some basic recommendations to the MDCH administration.

The third meeting was intended to explore four fundamental questions:

- 1) What constitutes a valid "patient-provider" relationship?*
- 2) Should "telehealth" providers be required to be licensed or registered by the State of Michigan?*
- 3) Proposed Board of Pharmacy E-prescribing rules (from the 2001 Task Force recommendations): Do the rules have a broader application?*
- 4) How does the current reimbursement system have to change in order to support telehealth?*

Resource documents distributed at the meeting led to extensive discussion surrounding the importance and complexity of E-Health issues. In addition, the group became very focused and engaged on the first discussion question. The "patient-provider" relationship was discussed at length, such that a discussion of the other three questions was postponed to the next meeting.

The fourth meeting explored four fundamental questions:

- 1) What constitutes a valid "patient-provider" relationship?*
- 2) Should "telehealth" providers be regulated?*
- 3) What unique confidentiality issues need to be regulated?*

4) *How does the current reimbursement system need to change to support telehealth?*

Each of the four questions was discussed at this meeting. A good deal of consensus was reached on each of these critical points of E-Health policy and regulation. It was decided that staff would draft a paper and recommendations based on 1) discussions at the meetings, 2) an additional literature review, 3) online investigation of E-health information, 4) a review of current federal and Michigan law affecting E-Health, and 5) E-Health policies and statutes of other states.

The first draft of this paper was completed in August 2007. The E-Health Workgroup was provided an electronic copy of the draft document to review and approve the content and recommendations. The Workgroup re-convened in October 2007 to discuss the recommendations and needed corrections to the document.

## VI. RECOMMENDATIONS OF THE E-HEALTH WORKGROUP

1. MDCH should adopt the Federation of State Medical Board's *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* and communicate this to all health care providers through appropriate Department websites and other appropriate communication channels.
2. Michigan should regulate (with a "special purpose license") all health care professionals regulated under Article 15 who provide health care services or consultation via telehealth across state lines to Michigan patients. Any health care delivered to Michigan residents across state lines through any technologically facilitated means shall be considered to be taking place in Michigan.. This legislation would be based on the Federation of State Medical Board's Model Act to Regulate the Practice of Medicine across State Lines.
3. Because all telehealth across state lines to Michigan residents shall be considered to be delivered in Michigan, Section 333.16171(h) of the Public Health Code (which describes an exception for state licensure for health care providers from bordering states whose practice extends into Michigan, but who do not have an office or designated place to meet patients in Michigan) should be amended to indicate that regulated health care providers using Telehealth would not qualify for this exemption from Michigan licensure.
4. MDCH should include, by statute, a definition of E-health as part of the practice of medicine, and address the issues of the patient-provider relationship, confidentiality, and privacy. The statute should identify E-Health as being held to the same standards of all medical practice.
5. A "patient encounter" should be defined by statute to include any health care delivered by a health care provider to a patient through any technologically facilitated form of provider-patient communication. This statute should describe which, if any, health professions may engage in E-Health patient encounters through any means of

technologically facilitated communication without first having an initial face-to-face encounter.

6. MDCH should communicate to private payers our recommendation that they formally recognize and reimburse for E-Health services provided by health care providers. The MDCH Medicaid Office should also consider formally recognizing and reimbursing for all eligible health care services provided through means of E-Health.
7. Licensing Boards should clearly communicate to their respective licensees the advantages, disadvantages, and risks of using E-health in the delivery health care. Boards should advocate that training in the appropriate use of E-health be part of a healthcare professional's continuous professional development.
8. MDCH should identify the provision of E-Health as an important component of the emerging healthcare industry on their websites (such as the Michigan Healthcare Workforce Center, Health Careers, and Michigan Center for Health Professions websites), publications, and other sources of information for the public and healthcare professionals and encourage similar recognition of E-Health by the Michigan Economic Development Corporation, Michigan Department of Labor and Economic Growth, and other appropriate state of departments.
9. MDCH should encourage all health professions to incorporate E-Health into the curriculum of all professional training programs, including the many privacy and ethical issues of such practices as email communication, provider-patient "blogs", and professional practice websites.
10. An E-Health website should be created that provides both the public and health care professionals with important information, Michigan policies and relevant statutes, activities in other states, federal policies, resource documents, and other information regarding E-Health practices. This website should also contain information regarding the past, current, and future activities of any workgroup, task force, commission, or other official state body focused on E-Health.
11. Complete the E-prescribing recommendations regarding pharmacy administrative rules developed in 2001 (**Attachment J**).
12. The State Legislature and MDCH should amend existing statutes and enact new statutes that address the unfinished e-prescribing recommendations detailed in Table 1 of the 2001 Task Force on Internet Pharmacies Report (**Attachment J**).
13. The Michigan Legislature and MDCH should enact legislation that establishes the National Association of Boards of Pharmacy's *Verified Internet Pharmacy Practice Sites (VIPPS)* standard for Internet pharmacies doing business in Michigan, as detailed in **Attachment J**.

14. The E-Health Workgroup should periodically reconvene to further explore and advise MDCH regarding a host of E-Health issues that may require new legislation, policy development, or staff action, such as the exploration of a state initiative to facilitate a statewide electronic health record, application for federal grants for E-Health pilot projects, the need for new E-Health legislation to help facilitate E-Health and protect the public, and addressing new technologies or new E-Health delivery issues.
15. MDCH should assure that state Medicaid policies are not a barrier to using E-Healthcare.

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## VIII. ATTACHMENTS

**ATTACHMENT A**

*E-Health Workgroup Member List*

## E-Healthcare Work Group Membership

<u>Member</u>	<u>Representing</u>
Roberta Armstrong, R.Ph.	Michigan Board of Pharmacy
John Barnas	Center for Rural Health
Perry Bell	Department of Community Health
Tom Bissonette, R.N.	Michigan Nurses Association
Melanie Brim, Chairperson	Department of Community Health
Nels Bullock	Center for Rural Health
Steven Creamer	Department of Community Health
Michael Davis, P.A.-C.	Task Force on Physician's Assistants
Stephen Durst, Pharm. D.	Ferris State University
Judith Kovach, Ph.D.	Michigan Psychological Association
Tim Laing, M.D.	Michigan Board of Medicine
Jim Lee	Michigan Health & Hospital Association
Howard Marderosian	Department of Attorney General
Karen McCoskey	Department of Community Health
Ronald Melaragni, R.Ph.	Michigan Pharmacy Association
Robert Miller	Department of Community Health
Peter Muller, M.D.	Michigan State Medical Society
Beth Nagel	Department of Community Health
Amy Perry, R.N.	Michigan Board of Nursing
Peter Pratt, Ph.D.	Public Sector Consultants

Amy Rosenberg	Department of Attorney General
Anne Rosewarne	Michigan Health Council
George Sawabini, D.O.	Michigan Osteopathic Association
Kim Sibilsky	Michigan Primary Care Association
Joe Stephansky, Ph.D.	Michigan Health and Hospital Association
Patricia Watson, Ph.D.	Michigan Board of Psychology
Frank Winters, D.O.	Michigan Board of Osteo. Med. & Surgery
Michael Wissel, R.Ph.	Department of Community Health

## **ATTACHMENT B**

### *E-Health Workgroup Meetings*

## **E-Healthcare Workgroup**

**September 9, 2005**

**10:00 a.m. to 12:00 p.m.**

**611 W. Ottawa, UP Level, Conf. Room 4**

**Lansing, Michigan**

### **Agenda**

10:00 – 10:15 a.m.	Welcome & Introductions Review of the Workgroup Charge
10:15 – 11:15 a.m.	Small Group Discussion
11:15 – 11:45 a.m.	Debriefing
11:45 – 12:00 p.m.	Next Steps

**Michigan Department of Community Health  
Bureau of Health Professions**

**e-Healthcare Workgroup  
September 9, 2005**

Response to Discussion Questions

**1. *What does “e-Healthcare” mean to you when you think about the delivery of health care?***

- Robotic surgery
- Electronic access to medical records
- Connectivity/sharing of records/test results
- Issues about territory and regulations in different states, crossing state lines and internationally
- Advantage for distance learning
- Universal standards should try to be established
- Instant information will improve patient care
- Include audio as well as internet and email
- Should face to face relationship be established first
- Insurance/reimbursement issues
- E-prescribing
- Consider benefits for rural areas
- HIPAA and confidentiality issues
- Patient/physician relationship (contact/person to person)
- Location (i.e. physician in other states)
- Keep within state or global (more issues may arise)
- Enable collaboration between professionals (nurse, doctor and specialist)
- Quality of service
- Out-of-state patient
- Flow of information between individuals
- Electronic records (private physicians) – Paper records to electronic (time frame & cost)
- History of patient (personal records)
- E-prescribing (sign-off of controlled substances)
- Access

**2. *What are the benefits and risks associated with the utilization of the various technologies identified in the first question?***



## BENEFITS

- Decision support systems leading to error reduction
- Increase access
- Decrease costs
- Reduced travel
- Reduced paperwork
- Quality and safety/Increase in patient safety
- Decrease phone calls for clarification
- Record of transaction
- Decreased time of provider
- Consumers can better “manage” their care
- Records are legible
- Easy access to patient records could greatly improve patient care
- Decrease costs through reduction in duplicated services (e.g. ↓ hospitalizations)
- Information immediately available. Don’t have to rely on patient to remember
- Easily read-readable
- Physical distance for patients in rural areas
- Standardized medical record
- Standards of care
- Tracking of patient (diabetics, etc.)
- Data is researchable

## RISKS

- Regulation of practice – monitoring delegation
- Delegation issues (at the client end)
- Inability to get paid
- Confidentiality
- Privacy & security of data
- No back-up systems
- Unlicensed “providers”
- Valid prescriber-patient relationships
- For mental health – absence of non-verbal data.
- Access by individuals other than the patient.
- Malpractice
- Reimbursement
- HIPAA
- Cost of getting the system up and running/ongoing maintenance costs
- Competency of provider
- Licensure status (active, disciplined)
- Change in doctor/patient relationship ethics – face to face contact
- Mental health assessment
- Power outages
- Confidentiality
- Consent
- Abuse of system

**3. *In thinking about the final report of the workgroup, what other issues need to be included in the discussion portion of the document?***

- Survey vendors
- Connection (talk to one another)
- Portals (i.e. AOL) state-wide
- Standards and policies (more equal)
- Licensure and regulations
- Dr. visit patient/Patient visit Dr.
- Ongoing consultation with patient
- Scope of practice
- Look at Veteran's Administration
- Training of staff – use of all equipment
- How Internet impacts and funding – security
- Flow of information – interfacing
- Personal ID card with information or chip
- Dependent providers
- Global economic benefits – would decrease duplicate care
- Funding to interconnect system elements
- Tax incentives
- Peer to peer vs. centralized repository
- Alignment to regulations and reimbursement
- Delegation to unknown medical personnel could present problems
- HIPAA barriers
- E-health opportunities
- Consumer protection
- Statutory changes to address new technology
- Consumer cost benefits
- AARP
- Population management
- Widespread sharing of drug interactions, etc.
- Access to “real time” data.
- Include IT, consumer and insurance perspectives in the discussion.

September 14, 2005

## **E-Healthcare Workgroup**

**November 18, 2005  
10:00 a.m. to 12:00 p.m.  
600 W. St. Joseph, Ste. 10  
Lansing, Michigan**

### **Agenda**

10:00 – 10:20 a.m.	Welcome & Introductions Review Meeting Materials: <ul style="list-style-type: none"><li>- Agenda</li><li>- Assignment Sheet</li><li>- Handouts</li><li>- Reference Materials</li></ul>
10:20 – 11:00 a.m.	Proposed Project Outline – Discussion/Input
11:00 – 11:45 a.m.	Strategies for Structuring Group Discussion Discussion/Input
11:45 – 12:00 p.m.	Review Proposed Timelines & Next Steps

**Michigan Department of Community Health  
Bureau of Health Professions**

**E-Healthcare Work Group  
November 18, 2005**

**Meeting Notes**

1. Beth Perrine talked about a federal grant DCH received from the Department of Health and Human Services (HHS). Grant was received on 10/1/2005. Grant is being managed by Cyber Michigan, an entity organized under Altarum. Will be hosting an open session for key stakeholders on December 14 at the Kellogg Center.

The focus of the grant is interoperability and health information network.

2. Provider competency
  - \* Clinical decision support system (proprietary).
    - One of the questions that are likely to come up is where the standards come from.
    - Questions about discoverability of information.
3. Cost of the infrastructure is a major impediment to interoperability and development of the network.
4. Need to discuss the alignment of regulations to reimbursement policies. Pathways are the same.
5. Focus on where there will likely be major cost savings. Make a business case for use of technology and building the infrastructure.
6. Discuss standards for electronic signatures. Would be best if there were national standards.
7. Emphasize cost savings related to implementation of e-prescribing. Opportunity already exists. Need to set standard for transmission of orders. Biggest E-opportunity. Alaska – very advanced.
8. There needs to be a transition strategy as we move from the current system to an integrated network.
9. Avoid anything that inhibits the use of midlevel practitioners (PAs, nurse practitioners).

10. Consider the impact of federal legislation
  - a) Stark issues
  - b) HIPAA
11. Other states that we should look at include Idaho and Montana.
12. RHIO – Regional Health Information Organization
  - \* Information flows between organizations without barriers.
  - \* RHIO serves somewhat like a hub, resulting in a formstructure vs. more informal health information networks.
  - \* Need to encourage development of networks.
  - \* Should be standard policies for security, privacy, transmission.
13. Japan – web based systems
14. “Continuity of care record” do internet search. Check Massachusetts Medical Society. Looking for information on “interim health record”. May be one of the transmission issues.
15. Clarify that “AARP” under miscellaneous issues referred to having a representative from AARP on the work group.
16. Peter Pratt mentioned that the past issue of the Health Affairs Journal was all about E-Healthcare.

## **E-Healthcare Workgroup**

**May 19, 2006  
10:00 a.m. to 12:00 p.m.  
201 Townsend Street, 7<sup>th</sup> floor  
Executive Conference Room  
Lansing, Michigan**

### **Agenda**

9:30 a.m.	Refreshments
10:00 – 10:15 a.m.	Project review
10:15 – 11:15 a.m.	Focus groups
Group #1:	What constitutes a valid “patient-provider” relationship?
Group #2:	Should “telehealth” providers be required to be licensed or registered by the State of Michigan?
Group#3:	Proposed Board of Pharmacy E-prescribing rules: Do they have a broader application?
Group#4:	How does the current reimbursement system have to change in order to support telehealth?
11:15 – 11:45a.m.	Debriefing
11:45 – 12:00p.m.	Next steps

June 9, 2006

**TO:** E-Healthcare Workgroup Members  
(that did not attend the May 2006 meeting)

**FROM:** Melanie Brim, Director  
Bureau of Health Professions

**SUBJECT:** May 2006 Meeting Handouts

The following materials were distributed at the E-Healthcare Workgroup meeting on May 19, 2006. Copies are attached for your review.

- Federation of State Medical Boards (FSMB) Legislative Report, Activity through April 30, 2006 – portion of the report specifically addressing telemedicine legislation
- Excerpt from the 2005 FSMB Legislative Report dealing with telemedicine legislation enacted in 2005
- Excerpt from the 2005 FSMB Legislative Report that covers legislative that was pending in 2005
- Copy of proposed legislation from the New York Assembly that would enact the “telemedicine access act”
- Copy of a recent Colorado statute that addresses portability of health care professional licenses
- Draft rules of the Michigan Board of Pharmacy that address electronic prescribing (rules have been to public hearing and will likely be final within the next 90 days)
- Copy of a 2005 statute in Colorado dealing with regulation and reimbursement of health care services provided through telehealth or telemedicine under the state Medicaid program
- Copy of New Mexico statute that establishes a telehealth commission

These documents were used, in part, to facilitate discussion on the four issues identified on the meeting agenda:

- 1) What constitutes a valid “patient-provider” relationship?
- 2) Should “telehealth” providers be required to be licensed or registered by the State of Michigan?
- 3) Proposed board of Pharmacy E-prescribing rules: Do they have a broader application?
- 4) How does the current reimbursement system have to change in order to support telehealth?

Over the next two months we will be scheduling a number of smaller meetings to focus on each of the above issues. Additional background information may be provided in advance of the meetings depending on the topic. Workgroup members will be encouraged to attend as

many of the small group meetings as possible. Participation will also be open to individuals who are not formally part of the workgroup. Information on the meetings will be forthcoming. If you know of someone who has a particular interest in one of the above topics, please feel free to extend an invitation.

If you have any questions about the attached material or the upcoming small group meetings, please do not hesitate to contact me at [mbbrim@michigan.gov](mailto:mbbrim@michigan.gov) or (517) 373-8165.



## **E-Healthcare Workgroup**

**December 8, 2006  
10:00 a.m. to 12:00 p.m.  
611 W. Ottawa, UP Level, Room 4  
Lansing, Michigan**

### **Agenda**

- |                    |   |
|--------------------|---|
| 9:30 a.m.          | Refreshments  |
| 10:00 – 10:10 a.m. | Welcome and Introductions   |
| 10:10 – 10:20 a.m. | Review of project objectives and deliverables                                   |
| 10:20 – 11:20 a.m. | Focused Discussion Groups   |
| Group #1:          | What constitutes a valid “patient-provider” relationship?                       |
|                    | Facilitator: Steve Creamer  |
| Group #2:          | Should “telehealth” providers be regulated?                                     |
|                    | Facilitator: Perry Bell   |
| Group#3:           | What unique confidentiality issues need to be addressed?                        |
|                    | Facilitator: Kate Lum   |
| Group#4:           | How does the current reimbursement system need to change to support telehealth? |
|                    | Facilitator: Melanie Brim   |
| 11:20 – 11:50 a.m. | Feedback Session  |
| 11:50 – 12:00 p.m. | Wrap-up   |

## **E-Healthcare Workgroup**

**December 8, 2006**

### **1) What constitutes a valid “patient-provider” relationship?**

- Record created
- ID of patient, provider
- Record of encounter
- When does the relationship start?
  - Traditional model
  - Traditional initial and follow-up electronically
  - Will vary with nature of the need/service e/g/ 2<sup>nd</sup> opinion, consult
- What wouldn't be a valid relationship?
  - “In-person” requirements vs. services which don't have an “in-person” component
  - “Best case” – shouldn't be the standard
  - Ability to communicate back to remote providers
  - Some exceptions
    - ✓ “Relationship begins when provider has data necessary under the standard of care to treat the patient”
    - ✓ The “loop”
      - ◆ Standard of care includes availability of follow-up
    - ✓ “Face to face?” – what does it mean?
      - ◆ Could you build in acceptable exceptions?
        - Web-cam, teleconferencing, face to face visits.

### **2) Should “telehealth” providers be regulated?**

- YES – unanimous!
- How
  - MSMS – all need licenses
    - ✓ Important for public accountability/regulation
  - Be more explicit in what licensees will be defining e-healthcare and it's “scope”
  - Separate “e-health” license
- What is “supervision”- less assessable to physicians supervisions
  - Available in software – not all physicians are physically present (but electronically present?)
  - Telephone or computer (e-mail)
  - Software that recognizes when supervision is needed
  - Statute to facilitate the software
- Other states
  - A license here would require you to comply with the Michigan Public Health Code
  - Identifying

- 3) **What unique confidentiality issues need to be addressed?**
  - HIPPA – currently
  - Need written agreement (Mental Health)
  - Errors – mistaken identity
  - Unintentional breach
  - Do we hold telehealth providers to higher standards?
  - Technology (how it will answer some of the issues)
- 4) **How does the current reimbursement system need to change to support telehealth?**
  - Volume – currently
  - Volume and quality
  - Interval care
  - Charging for calls
  - Medicaid needs to be part of the e-health
  - Other state models

**ATTACHMENT C**

*American Medical Association Communication  
Guidelines for Email*

The AMA has suggested the following guidelines be adopted.

### **Communication Guidelines for E-mail**

- a. Establish turnaround time for messages. Exercise caution when using e-mail for urgent matters.
- b. Inform patient about privacy issues.
- c. Patients should know who besides addressee processes messages during addressee's usual business hours and during addressee's vacation or illness.
- d. Whenever possible and appropriate, physicians should retain electronic and/or paper copies of e-mails communications with patients.
- e. Establish types of transactions (prescription refill, appointment scheduling, etc.) and sensitivity of subject matter (HIV, mental health, etc.) permitted over e-mail.
- f. Instruct patients to put the category of transaction in the subject line of the message for filtering: prescription, appointment, medical advice, billing question.
- g. Request that patients put their name and patient identification number in the body of the message.
- h. Configure automatic reply to acknowledge receipt of messages.
- i. Send a new message to inform patient of completion of request.
- j. Request that patients use auto reply feature to acknowledge reading clinicians message.
- k. Develop archival and retrieval mechanisms.
- l. Maintain a mailing list of patients, but do not send group mailings where recipients are visible to each other. Use blind copy feature in software.
- m. Avoid anger, sarcasm, harsh criticism, and libelous references to third parties in messages.
- n. Append a standard block of text to the end of e-mail messages to patients, which contains the physician's full name, contact information, and reminders about security and the importance of alternative forms of communication for emergencies.
- o. Explain to patients that their messages should be concise.
- p. When e-mail messages become too lengthy or the correspondence is prolonged, notify patients to come in to discuss or call them.
- q. Remind patients when they do not adhere to the guidelines.
- r. For patients who repeatedly do not adhere to the guidelines, it is acceptable to terminate the e-mail relationship.

### **Medico Legal and Administrative Guidelines:**

- a. Develop a patient-clinician agreement for the informed consent for the use of e-mail. This should be discussed with and signed by the patient and documented in the medical record. Provide patients with a copy of the agreement. Agreement should contain the following:
  - b. Terms in communication guidelines (stated above).
  - c. Provide instructions for when and how to convert to phone calls and office visits.
  - d. Describe security mechanisms in place.

- e. Hold harmless the health care institution for information loss due to technical failures.
- f. Waive encryption requirement, if any, at patient's insistence.
- g. Describe security mechanisms in place including:
- h. Using a password-protected screen saver for all desktop workstations in the office, hospital, and at home.
- i. Never forwarding patient-identifiable information to a third party without the patient's express permission.
- j. Never using patient's e-mail address in a marketing scheme.
- k. Not sharing professional e-mail accounts with family members.
- l. Not using unencrypted wireless communications with patient-identifiable information.
- m. Double-checking all "To" fields prior to sending messages.
- n. Perform at least weekly backups of e-mail onto long-term storage. Define long-term as the term applicable to paper records.
- o. Commit policy decisions to writing and electronic form.

The policies and procedures for e-mail and facsimile must be communicated to all patients who desire to communicate electronically and by fax. (BOT Rep. 2, A-00; Modified: CMS Rep. 4, A-01 and BOT Rep. 24, A-02)

## **ATTACHMENT D**

*Working Group for Healthcare's Guidelines  
for Online Communication*

# eRisk Working Group for Healthcare's Guidelines for Online Communication

January 2007

The *eRisk Guidelines* have been developed by the eRisk Working Group for Healthcare, a consortium of professional liability carriers, medical societies and state licensure board representatives. These Guidelines are meant to provide information to healthcare providers related to the use of online communication and services with patients. They are reviewed and updated regularly. These Guidelines are not meant as legal advice and clinicians are encouraged to bring any specific questions or issues related to online communication to their legal counsel.

## General Principles

The legal rules, ethical guidelines and professional etiquette that govern and guide traditional communications between the healthcare provider and patient are equally applicable to email, Web sites, list serves and other electronic services and communications, including the use of Personal Health Records (PHRs) with patients. A Personal Health Record (PHR) is established, owned and controlled by the patient or their caregiver. An Electronic Medical Record (EMR) is a practice-based clinical record that is established, owned and controlled by the practice. However, the technology of online communications introduces special concerns and risks as follows:

1. **Confidentiality.** The healthcare clinician is responsible for taking reasonable steps to protect patient privacy and to guard against unauthorized access to and/or use of patient healthcare information. This responsibility extends to the use of network services that have an appropriate level of privacy and security as required under HIPAA. Following are key considerations:
  - a. **Privacy and Security.** Online communications between healthcare clinicians and patients should be conducted over a secure network, with provisions for privacy and security, including encryption, in accordance with HIPAA. Standard email services do not meet the requirements under HIPAA. Healthcare clinicians need to be aware of the full range of potential privacy and security risks and the requirements under HIPAA designed to mitigate those risks, and develop policies and procedures accordingly.

*Note: With respect to email specifically, clinicians are encouraged to add a disclosure to the bottom of their standard, non-secure email service stating that "this email is not secure, and is not for use by patients or for healthcare purposes in general".*

- b. **Authentication.** Healthcare clinicians have responsibility for taking reasonable steps to authenticate the identity of correspondent(s) in electronic communication and to ensure that recipients of information are authorized to receive it. Patient authentication or authentication of an authorized patient proxy (i.e., parent of a minor, authorized family member, etc.) for patient-provider online communication including the delivery of patient data is important in order to ensure patient privacy



and confidentiality. Clinicians are encouraged to follow the following guidelines for patient authentication:

- i. Have a written patient authentication protocol for all practice personnel and require all members of the staff to understand and adhere to the protocol.
  - ii. Establish minimum standards for patient authentication when a patient is new to a practice or not well known.
  - iii. Keep a written record, electronic or on paper, of each patient authenticated for online communication or data exchange. The record should include the following:
    1. Name of the patient
    2. Date of authentication
    3. Name of practice staff authenticating the patient
    4. Means used to authenticate the patient
  - iv. Providers should take care not to offer, promote or encourage patients to participate in online healthcare services where patient authentication is not addressed to at least the level offered by the provider in his/her own practice.
2. **Unauthorized Access to Computers.** Unauthorized physical access to computers can immediately compromise patient information or put that information at risk through compromise of the security of the computers. Practices should establish and follow procedures to guard against unauthorized access to computers with technologies such as automatic log-out and password protection.
3. **Informed Consent.** Prior to the initiation of online communication between healthcare clinician and patient, informed consent should be obtained from the patient regarding the appropriate use and limitations of this form of communication. Clinicians should develop and adhere to specific written guidelines and protocols for online communications with patients, such as avoiding emergency use, heightened consideration of use for highly sensitive medical topics, and setting expectations for response times. These guidelines should be documented in the clinician's practice policy manuals, in patient terms of service or disclosures, or in the medical record when appropriate.

Clinicians should exercise discretion when selecting patients for the use of online services to ensure that they are capable of electronic communication and will be compliant. Practices should consider developing patient use guidelines to help clinicians decide who uses these services on a patient-specific basis.

4. **Pre-Existing Clinician-Patient Relationship.** Healthcare clinicians may increase their liability exposure by initiating a clinician-patient relationship online. Payment for online services may further increase that exposure. Online communications of any kind are best suited for patients previously seen and evaluated in an office setting.
5. **Licensing Jurisdiction.** Online interactions between a healthcare clinician and a patient are subject to requirements of state licensure. Communications online with a patient, outside of the state in which the clinician holds a license, may subject the clinician to increased risk. For example, pathologists, radiologists and other clinicians interpreting specimens, slides or images sent through interstate commerce for a primary diagnosis that becomes part of the patient's medical record, should have a license to practice medicine in the state in which the patient presents for diagnosis or where the specimen is

taken or image is made. Intra-specialty consultation does not require in-state licensure, provided the consultation is requested by a physician licensed within the state and is referenced in a report they issue.

6. **Sensitive Subject Matter.** Clinicians should advise patients of the risks that information the patient may consider sensitive inadvertently may be accessed by someone not authorized to see it. Physicians may wish to specifically list examples of sensitive information such as mental health, substance abuse, reproductive history, sexually transmitted diseases, drug and alcohol problems, genetic disorders and HIV status to their patients for their consideration.

Some states have laws about special classes of health information, such as HIV or mental health. Clinicians should follow state law in obtaining approval from the patient to exchange those classes of information with patients. Some states may prohibit electronic transfer of specific classes of information regardless of patient consent.

7. **Patient Education and Care Management.** Healthcare clinicians are responsible for the information that they make available to their patients online. Information that is provided to patients through a PHR, automated patient education programs, care management and other online services should come either directly from the healthcare clinician or from a recognized, credible and authoritative source.
8. **Emergency Subject Matter.** Healthcare clinicians should advise patients of the risks associated with online communication related to emergency medical subjects such as chest pain, shortness of breath, high fever, and physical trauma or bleeding during pregnancy. Clinicians should discourage the use of online communication to address medical emergencies and instead instruct patients to call the office or go to an emergency department. In addition, patients should be referred to the Online Consultation Terms of Service where they have accepted the condition that the Online Consultation service is not to be used for emergency issues. Physicians should consider using a disclaimer on web pages and emails reminding patients that emergency subject matter is not appropriate for electronic communication.
9. **Medical Records.** A permanent record of online communications relevant to the ongoing medical care of the patient should be maintained as part of the patient's medical record, whether that record is paper or electronic. All clinically-relevant online clinician-patient and clinician-clinician communications (including email) should be a permanent part of the medical record. Accurate and thorough documentation is effective risk management.

Providers and patients should be aware that email and online information, including PHRs and consultations, are not erased from the hard drive when deleted and are potentially discoverable in litigation. Therefore all communicated information should be accurate and professional.

As interoperability between technology-based services (such as an EMR and PHR) become more common, if a patient is allowed to electronically transmit information to a clinician, that information should be quarantined until the clinician has reviewed and commented on the data, to avoid introducing inappropriate or incorrect information into the clinicians' medical record.

10. **Practice Web Site Considerations.**
- a. **Authoritative Information.** Healthcare clinicians are responsible for the information they make available to their patients online. Information that is provided on a medical practice Web site or provided to a specific patient via secure email or other online services should come either directly from the healthcare clinician or from a recognized and credible source.
  - b. **Commercial Information.** Web sites and online communications of an advertising, promotional or marketing nature may unrealistically raise patient expectations and subject clinicians to increased liability, including implicit guarantees or implied warranty and potential violation of consumer protection laws designed to protect against deceptive business practices. This is particularly true when cosmetic procedures, off-label drug use, and non-FDA approved procedures are promoted.
  - c. **Links to Third Party Web Sites and Other Sources of Information.** Clinicians are encouraged to post a disclaimer page between their Web site and a link to any third party Web site/information that advises patients and other viewers that they are leaving the clinician practice Web site and that the clinician and the practice does not assume any responsibility for the content or the privacy of other Web sites to which the practice Web site links.

### **Online Clinical Consultations**

An Online Clinical Consultation is a clinical consultation between a clinician and a patient, similar to an office visit or a call that would be documented in the patient's chart, but conducted online via a secure messaging service. In an online clinical consultation, the clinician has the same obligations for patient care and follow-up as in face-to-face, written and telephone consultations. An online consultation should be substantive and specific to the patient's personal health status.

In addition to the 10 guidelines stated above, the following are additional considerations for fee-based online consultations:

- 1. **Informed Consent.** Prior to initiating an online consultation, the healthcare clinician should obtain the patient's informed consent to participate in the consultation, including discussing appropriate expectations, disclaimers and service terms,, and any fees that may be imposed. This consent can be presented as part of a Terms of Service the patient must accept either online or in writing before engaging in online consultations.
- 2. **Fee Disclosure.** Prior to an online consultation, patients should be clearly informed about any charges that might be incurred, and be made aware that the charges may not be reimbursed by the patient's health insurance.
- 3. **Identity Disclosure.** Clinical information that is provided to the patient during the course of an online consultation should come from, or be reviewed in detail by, the consulting clinician whose identity should be made clear to the patient.
- 4. **Available Information.** Healthcare clinicians should state and document, within the context of the consultation or clearly within the patient terms of service agreed to in advance of requesting an online consultation, that the consultation is based only upon information made available by the patient to

the clinician during, or prior to, the online consultation, including referral to the patient's chart when appropriate, and therefore may not be an adequate substitute for an office visit.

5. **Online Consultation vs. Online Diagnosis and Treatment.** Clinicians should distinguish between an online consultation related to a known pre-existing condition (such as those concerning ongoing treatment and follow-up questions) - - and the diagnosis and treatment of new conditions addressed for the first time online. The diagnosis and treatment of new conditions online may compromise patient safety and increase liability exposure. When clinicians decline to diagnose a new condition online, they should communicate the importance of immediate office follow-up to the patient and document this in their office medical record. When the patient presents at the office, clinicians should document the time lapse between their deferral of the online consultation and the patient's arrival in the office.
6. **Follow-Up Plans.** An online consultation should include an explicit follow-up plan, as clinically indicated, that is clearly communicated to the patient.
7. **Internet Pharmacies.** There are potential risks when patients are referred to on-line pharmacies, since some employ "cyberdocs" who dispense drugs and medical devices without a valid doctor's order and others may be involved in the illegal importation of prescription drugs. The National Association of Boards of Pharmacy has a Verified Internet Pharmacy Practice Sites (VIPPS) program (<http://www.nabp.net/vipps/intro.asp>). Pharmacies in compliance with their standards show the VIPPS seal of approval on their home page.

### **Personal Health Records**

Personal Health Records (PHRs) -- the electronic storage and exchange of patient information, which may include electronic patient education, FDA and medical device warnings, disease management, and other programs -- have the potential to improve care quality and efficiency. PHR and related information technology services are now being promoted by the government, health plans, employers, patient advocacy groups and others.

The technology of PHR and other patient-specific information technology services introduce special concerns and potential risks. When clinicians offer a PHR service to their patients, the patients/caregivers should be required to accept a PHR Terms of Service, either online through the PHR service provided or in writing from the practice, which at a minimum should include the following:

1. The PHR service is provided to patients for their convenience only, and is distinct from the medical record maintained by the physician or healthcare provider. Entries in the PHR do not become part of the medical record unless and until they are formally accepted for inclusion by the clinician. When information is imported from a PHR into the clinician's record, its origin should be documented.
2. It should be made clear to patients that physicians are not responsible for knowing the information contained within a PHR except when they have consulted it in association with a formal office visit or Online Consultation.
3. It is the patient's responsibility to notify their healthcare clinician(s) if they have a PHR.

4. The PHR is not a substitute for directly communicating the patient's medical information to his or her physician in a traditional format (in-person, by telephone, etc.). Patients should not assume that their Personal Health Record has ever been seen or reviewed by their clinician(s).
5. It is the patient's responsibility to notify their healthcare provider(s) when new information appears in their PHR - whether they personally update it or it is automatically updated by third parties (health plans and other insurers, pharmacies, laboratories, etc.). Entering information into this record does not guarantee that their clinician will see it.
6. The provider should make it clear that the responsibility for the accuracy of the information in the PHR remains with the patient or caregiver as the owner of the record.
7. Developing and maintaining a PHR on a clinician practice Web site requires that patients have a pre-existing relationship with that clinician.
8. Materials and information available through the PHR are for informational purposes only and are not a substitute for professional medical advice.
9. Patients/caregivers should agree that they will contact their clinician if they have any questions about their medical condition, or if they need medical help.
10. Patients/caregivers should agree that if they need emergency medical help, they should immediately call 911, their local emergency number, their physician, or go to an emergency department.
11. Patients/caregivers should agree that their User ID and Password are their responsibility to protect from unauthorized access and use by third parties.

All clinicians are advised to have Terms of Service and other legal documents, including Informed Consent, etc. reviewed by their legal counsel.

## **ATTACHMENT E**

*FSMB Model Guidelines for the Appropriate Use of the  
Internet in Medical Practice*



FEDERATION OF STATE MEDICAL BOARDS  
OF THE UNITED STATES, INC.

## **Model Guidelines for the Appropriate Use of the Internet in Medical Practice**

# **Model Guidelines for the Appropriate Use of the Internet in Medical Practice**

**A Policy Document of the Federation of State Medical Boards of the United States,  
Inc.**

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc.  
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# Report of the Special Committee on Professional Conduct and Ethics

## Introduction

In April 2000, the Federation's House of Delegates adopted 15 recommendations issued by the Special Committee on Professional Conduct and Ethics focusing on physician behaviors and practices which negatively impact (1) patient safety and welfare, and/or (2) the physician-patient relationship.

The recommendations pertain to physician activities in five specific areas:

- Disruptive behavior by physicians
- The sale of goods from physician offices
- Boundary issues and patient surrogates
- Participation in business or contractual relationships
- Regulation of Internet prescribing

Recommendation Nine of the Special Committee's Report called for the Federation of State Medical Boards to study the practice of medicine via the Internet as to the impact on public health and safety and develop guidelines for state medical boards to use in educating licensees as to the appropriate use of the Internet in medical practice. Then Federation President George C. Barrett, MD, extended the charge of the Special Committee on Professional Conduct and Ethics to fulfill the adopted recommendation.

In developing the guidelines that follow, the Committee evaluated current and projected use of the Internet in the delivery of health-care services and identified two distinct areas of e-health: health information and delivery of patient care. The Committee focused the guidelines on the latter due to its direct impact on patient safety and welfare and the physician-patient relationship.

# Model Guidelines for the Appropriate Use of the Internet in Medical Practice

## Section One. Preamble

The Internet has had a profound impact on the practice of medicine and offers opportunities for improving the delivery and accessibility of health care. Studies show a growing number of physicians are utilizing the Internet to some degree in their practices and patients want to receive certain medical services online.<sup>1</sup> However, patient safety concerns, especially as related to providing medical services via the Internet, including prescribing and dispensing medications, have created complex regulatory challenges for state medical boards in protecting the public.

The (name of board) recognizes that the Internet offers potential benefits in the provision of medical care. The appropriate application of this technology can enhance medical care by facilitating communication with physicians and other health care providers, refilling prescriptions, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information and clarifying medical advice. However, it is the expectation of the Board that e-mail and other electronic communications and interactions between the physician and patient should supplement and enhance, but not replace, crucial interpersonal interactions that create the very basis of the physician-patient relationship.

The Board has developed these guidelines to educate licensees as to the appropriate use of the Internet in medical practice. The (name of board) is committed to assuring patient access to the convenience and benefits afforded by the Internet while promoting the responsible practice of medicine by physicians. It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain a high degree of professionalism and should:

- Place the welfare of patients first
- Maintain acceptable standards of practice
- Adhere to recognized ethical codes governing the medical profession
- Properly supervise physician extenders
- Protect patient confidentiality

<sup>1</sup> AMA. Report of the Council on Medical Services, Medical Care Online

## Section Two. Parity of Professional and Ethical Standards

There should be parity of ethical and professional standards applied to all aspects of a physician's practice. Related to the use of the Internet in a physician's practice, the Board expects the following ethical standards to be observed:

### Candor:

Physicians have an obligation to disclose clearly information (financial, professional or personal) that could influence patients' understanding or use of the information, products or services offered on any Web site offering health care services or information.

### Privacy:

Physicians have an obligation to prevent unauthorized access to or use of patient and personal data and to assure that "de-identified" data cannot be linked back to the user or patient.

### Integrity:

Information contained on Web sites should be truthful and not misleading or deceptive. It should be accurate and concise, up-to-date, and easy for patients to understand. Physicians associated with medical Web sites should strive to ensure that information provided be supported by current medical peer review literature, emanates from a recognized body of knowledge and conforms to minimal standards of care. It should clearly indicate whether it is based upon scientific studies, expert consensus, professional experience or personal opinion.

### Informed Consent:

Delivery of medical services via the Internet requires expanded responsibility on the part of the physician in informing and educating the patient. A patient has the right to know what personal data may be gathered and by whom. The physician must obtain material and informed consent from the patient to collect, share or use personal data. It should be clearly explained to patients when online communication should not take the place of a face-to-face interaction with a health care provider.

### Accountability:

Physicians have an obligation to provide meaningful opportunities for patients to give feedback about their concerns and to review and respond to those concerns in a timely and appropriate manner.

### Section Three. An Appropriate Physician-Patient Relationship

The health and well-being of patients depends upon a collaborative effort between physician and patient.<sup>2</sup> The relationship between physician and patient is complex and is based on the mutual understanding between physician and patient of the shared responsibility for the patient's health care. Although the Board recognizes that it may be difficult in some circumstances, particularly in an online setting, to define precisely the beginning of the physician-patient relationship, it tends to begin when an individual seeks assistance from a physician with a health-related matter for which the physician may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician (or other supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities and patient rights associated with establishing and maintaining an appropriate physician-patient relationship whether or not interpersonal contact between physician and patient has occurred.

### Section Four. Definitions

For the purpose of these guidelines, the following definitions apply:

"Medical Practice Site" means a patient-specific Internet site, access to which is limited to licensed physicians, associated medical personnel and patients. It is an interactive site and thus qualifies as a practice location. It requires a defined physician-patient relationship.

"General Health Information Site" means a non-interactive Internet site that is accessible by anyone with access to the Internet and intended to provide general, user non-specific information or advice about maintaining health or the treatment of an acute or chronic illness, health condition or disease state.

"Personal Health Information" means any personally identifiable information, whether oral or recorded in any form or medium, that is created or received by a physician or other health care provider and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual.<sup>3</sup>

"Physician-patient e-mail" means computer-based communication between physicians (or their medical personnel) and patients within a professional relationship in which the physician has taken on an explicit measure of responsibility for the patient's care.<sup>4</sup>

"Passive tracking mechanism" means a persistent electronic file used to track Web site navigation, which allows the Web site to record, and retain user-specific navigation information whenever the user accesses the Web site. Examples include "cookies," "clear gifs" or "Web bugs".<sup>5</sup>

"Web site" means an electronic source of health information content, commerce, connectivity, and/or service delivery.<sup>6</sup>

<sup>2</sup> AMA, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship

<sup>3</sup> Health Web Site Standards, Version 1.0, 2001 URAC

<sup>4</sup> Policy H-478.997, American Medical Association

<sup>5</sup> Health Web Site Standards, Version 1.0, 2001 URAC

<sup>6</sup> Health Web Site Standards, Version 1.0, 2001 URAC

## Section Five. Guidelines for the Appropriate Use of the Internet in Medical Practice

The Board has adopted the following guidelines for physicians utilizing the Internet in the delivery of patient care:

### Evaluation of the Patient

A documented patient evaluation, including history and physical evaluation adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided, must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise.

### Treatment

Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (face-to-face) settings. Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.

### Electronic Communications

Written policies and procedures should be maintained for the use of patient-physician electronic mail. Such policies and procedures should address (1) privacy, (2) health-care personnel (in addition to the physician addressee) who will process messages, (3) hours of operation, (4) types of transactions that will be permitted electronically, (5) required patient information to be included in the communication, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Sufficient security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions and laboratory results must be secure within existing technology (i.e., password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient's medical record.

Turnaround time should be established for patient-physician e-mail and medical practice sites should clearly indicate alternative form(s) of communication for urgent matters. E-mail systems should be configured to include an automatic reply to acknowledge message delivery and that messages have been read. Patients should be encouraged to confirm that they have received and read messages.

## Informed Consent

A written agreement should be employed documenting patient informed consent for the use of patient-physician e-mail. The agreement should be discussed with and signed by the patient and included in the medical record. The agreement should include the following terms:

- Types of transmissions that will be permitted (prescription refills, appointment scheduling, patient education, etc.)
- Under what circumstances alternate forms of communication or office visits should be utilized
- Security measures, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy
- Hold harmless clause for information lost due to technical failures
- Requirement for express patient consent to forward patient-identifiable information to a third party
- Patient's failure to comply with the agreement may result in physician terminating the e-mail relationship

## Medical Records

The medical record should include copies of all patient-related electronic communications, including patient-physician e-mail, prescriptions, laboratory and test results, evaluations and consultations, records of past care and instructions. Informed consent agreements related to the use of e-mail should also be filed in the medical record.

Patient medical records should remain current and accessible for review and be maintained in compliance with applicable state and federal requirements.

## Compliance with State and Federal Laws and Web Standards

Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy. Physicians are referred to "Standards for Privacy of Individually Identifiable Health Information" issued by the Department of Health and Human Services (HHS).<sup>7</sup> Guidance documents are available on the HHS Office for Civil Rights Web site at [www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa).

Physicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.<sup>8</sup>

Physicians are encouraged to comply with nationally recognized health Web site standards and codes of ethics, such as those promulgated by the American Medical Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC).

[7] Federal Register, December 28, 2000.

[8] FSMB: A Model Act to Regulate the Practice of Medicine Across State Lines (April 1996)

## Disclosure

Physician medical practice sites should clearly disclose:

- Owner of the site
- Specific services provided
- Office address and contact information
- Licensure and qualifications of physician(s) and associated health care providers
- Fees for online consultation and services and how payment is to be made
- Financial interests in any information, products or services
- Appropriate uses and limitations of the site, including providing health advice and emergency health situations
- Uses and response times for e-mails, electronic messages and other communications transmitted via the site
- To whom patient health information may be disclosed and for what purpose
- Rights of patients with respect to patient health information
- Information collected and any passive tracking mechanisms utilized

## Accountability

Medical practice sites should provide patients a clear mechanism to:

- access, supplement and amend patient-provided personal health information
- provide feedback regarding the site and the quality of information and services
- register complaints, including information regarding filing a complaint with the applicable state medical board(s)

## Advertising/Promotion of Goods or Products

Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits or incentives is prohibited.

## Links

Physician Web sites may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites.



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## **ATTACHMENT F**

*A Model Act to Regulate the Practice of Medicine Across State Lines  
(Federation of State Medical Boards of the United States of America)*

# **Report of the Ad Hoc Committee on Telemedicine**

## **Federation of State Medical Boards of the United States**

The Federation's governing body accepted the following Report of the Ad Hoc Committee on Telemedicine as policy in April 1996.

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### **A Model Act to Regulate the Practice of Medicine Across State Lines**

#### **Executive Summary**

##### **Section I. Background**

Traditional medical practice is being rapidly transformed by such factors as managed care, the politics of health care reform, as well as technological and other medical advances. Such advances, which include telemedicine, offer opportunities for improved health care delivery.

One aspect of these changes in the health care field is that medical practice may now be conducted over wide geographic areas. This challenges our nation's state-based medical licensure system to facilitate the growth of this evolving mode of patient care while maintaining a high standard of medical care and ensuring public protection.

While telemedicine has been evolving in the United States and abroad for the past 35 years, interest in the field has increased dramatically since 1990 due to the demand for accessible and cost-effective health care. Additionally, government support for the development and testing of sophisticated telecommunications systems has risen recently. Many federal agencies, including the Department of Commerce, the Health Care Financing Administration, the Office of Rural Health Policy, and the Department of Defense, have begun telemedicine research and demonstration programs to study the use of telemedicine over large distances.

Some of the potential benefits of telemedicine include increased access to health care (especially in underserved areas), expanded utilization of specialty expertise, rapid availability of patient records and reduced cost of patient care. There are, however, as yet unresolved issues surrounding telemedicine-medicine, including the regulation of physicians who practice across state boundaries.

Increased competitiveness in the medical marketplace has resulted in a marked increase in the practice of medicine across state lines. Pathological specimens are being shipped routinely to reference laboratories in distant states for processing and interpretation by pathologists. On occasion, the processed specimens may be distributed to pathologists in multiple states for interpretation. Radiographs are being transmitted electronically for interpretation to radiologists located hundreds of miles away from the point of patient contact. Telemedicine demonstration projects have clearly shown that current technology will allow a physician in a distant state to conduct "face-to-face" consultations with a patient in another state.

The Federation of State Medical Boards of the United States is committed to promoting high standards for physician licensure and practice and is actively involved in policy development, research, and education on behalf of its member boards. Because of the increase in the practice of medicine across state lines by telemedicine and other means and the implications for medical licensure, the Federation established a

special committee to evaluate the issues in this area and make recommendations to state medical boards regarding potential regulation.

Pursuant to this endeavor, the Federation's Ad Hoc Committee on Telemedicine studied and evaluated licensure issues involving telemedicine as well as the practice of medicine by other means across state lines. They reviewed recently enacted legislation in South Dakota, Kansas and Texas. Oral and written testimony was received by the committee from many sources, including the American Medical Association, the American Osteopathic Association, the American Telemedicine Association, the American College of Radiology, the American College of Cardiology, the American Board of Pediatrics, the C. Everett Koop Institute, the Mayo Clinic, and a number of state medical boards. Subsequently, the committee drafted a model act that would regulate telemedicine or medicine by other means across state lines for recommendation to state medical boards. Central to this regulatory statute is the establishment of a special license limited to the practice of medicine across state lines.

This executive summary has been developed to clarify the committee's rationale regarding each section of the model act in hopes of facilitating understanding and discussion of the proposal.

## **Section II. Legislative Findings and Purpose**

Due to technological and other advances, which now make possible the delivery of health care services across broad geographical areas, the number of physicians practicing medicine across state boundaries has increased in recent years and is expected to continue to increase in the foreseeable future. While it is desirable to facilitate such advances in medical practice, it is also necessary to establish appropriate regulations, which will ensure that high standards of patient care are maintained. As the practice of medicine across state lines increases, the possibility of adverse outcomes resulting from patient encounters will also increase.

Currently, physicians who practice medicine across state lines without physically being located in the state where the patient encounter occurs are either required to have a full and unrestricted license in that state or are unregulated. It is unacceptable to allow this type of practice to be unregulated, thereby denying the protection of the state to its citizens. However, physicians who are interested in providing their medical expertise in multiple jurisdictions may be daunted by the prospect of having to obtain full licensure in multiple states.

In response to these concerns (the need to protect the public without being overly burdensome to the profession), the committee developed a model legislative act which calls for an abbreviated but effective licensure process for physicians who will not be practicing physically within a state's jurisdiction, but wish to provide services to patients located within that jurisdiction. Such legislation would allow states to appropriately provide regulatory control over physicians providing services within their states. Such control is necessary for the protection of the citizens of the state.

## **Section III. Definition**

The practice of medicine across state lines is defined to include any medical act that occurs when the patient is physically located within the state and the physician is located outside the state. Any contact that results in a written or documented medical opinion and that affects the diagnosis or treatment of a patient constitutes the practice of medicine. This is true whether the physician and patient are connected through telecommunications or whether patient data (such as X-rays, EKGs, or laboratory tests) are transported by courier services or in some other manner. When the practice of medicine occurs as defined by the Medical Practice Act of an individual state in which the patient is located, then such practice should be subject to regulation by the patient's state medical board.

It is important to view the practice of medicine as occurring in the location of the patient in order that the full resources of the state would be available for the protection of that patient. The same standard of care,

already in existence in the patient's home state, would be required of all individuals practicing medicine within any jurisdiction, whether or not they were physically located outside of the state. The agency best able to ensure the maintenance of such standards in the protection of the patient is the medical board in the state of the patient's residence.

#### **Section IV. License Requirement**

The proposed model act would require physicians who want to engage in the practice of medicine across state lines by electronic or other means to obtain a special license issued by the state medical board. Such a license would be limited to the practice of medicine across state lines. It would not allow the physician to enter the state for the purpose of engaging in the practice of medicine.

#### **Section V. Issuance of License**

This committee's intent was to facilitate the acquisition of licensure in one or more jurisdictions by physicians wishing to practice across state boundaries. An individual holding a valid, unrestricted license in one state should be given every consideration for expedient issuance of a special license to regulate the practice of medicine across state lines in other states. This special license, once issued, would limit the physician solely to this type of medical practice and would prohibit the individual from physically practicing medicine within the state unless a full and unrestricted license was obtained.

While a state clearly has the option of denying such a special license based on grounds it concludes to be appropriate, including previous disciplinary action, the state is encouraged to issue such a license if it finds that the applicant would not present a threat to the public.

#### **Section VI. Effect of License**

To be effective in regulating this type of medical practice, this special license to regulate the practice of medicine across state lines must subjugate the licensee to the Medical Practice Act of the issuing state and to the regulatory authority of the state's medical board.

As required of licensed physicians practicing within the state, this license would require the licensee to agree to make himself available to the issuing state's medical board, along with any pertinent records. This requirement would be necessary to allow the board to fully investigate any complaints against such licensees. To ensure compliance with the board's investigation, a licensee who failed to appear or to provide the material requested by the board would be subject to the possible suspension or revocation of the special license until a formal hearing could be conducted. Any such action would be considered disciplinary in nature and reportable.

#### **Section VII. Patient Medical Records**

Concerns were raised regarding potential violations of laws and regulations concerning patient medical records currently in place in the patient's home state. To address these concerns, the model act requires that the licensee be subject to laws, rules and regulations governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within the state are maintained. This requirement is appropriate in that the patient should continue to enjoy the protection of confidentiality standards currently in place in his or her state. Such requirements are appropriate to safeguard the patient's medical records, regardless of the state where medical records are maintained.

#### **Section VIII. Exemptions**

The special purpose license would only be required of physicians who “regularly or frequently” engage in the practice of medicine across state lines. Each state medical board will define what constitutes the regular practice of such medicine. The practice of medicine across state lines will not fall under the provisions of the model, if the practice occurs less than once a month, involves less than ten patients on an annual basis, or comprises less than one percent (1%) of the physician’s diagnostic or therapeutic practice.

Importantly, it should be noted that physician-physician consultations, which occur from time to time and are traditional in the practice of medicine, would not be so regulated. It is noted that such consultations occur on an informal basis and are not usually the subject of expected compensation by the physician rendering such an informal consultation. The practice of medicine across state lines conducted as a result of a contractual relationship, however, would be considered “formal” and, therefore, be regulated by the Board.

The model act also exempts physicians who would engage in the practice of medicine across state lines in the event of an emergency. Again, the definition of an emergency situation would be defined by the Board in each state.

### **Section IX. Sanctions**

The model act provides provisions that an individual who would engage in the practice of medicine across state lines without this special license would be subject to prosecution for the unlicensed practice of medicine.

Additionally, the model act would not prohibit a state medical board from disciplining a physician located in its own jurisdiction who engaged in the practice of medicine across state lines and violated the state Medical Practice Act. It is appropriate that physicians remain under the regulation of their individual state medical boards even while holding special licenses limited to the practice of medicine in other states.

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## **An Act to Regulate the Practice of Medicine Across State Lines**

### **Legislative Findings and Purpose**

The legislature hereby finds and declares that, due to technological advances and changing practice patterns, the practice of medicine is occurring with increasing frequency across state lines and that certain technological advances in the practice of medicine are in the public interest. The legislature further finds and declares that the practice of medicine is a privilege and that the licensure by this State of practitioners outside this State engaging in such medical practice within this State and the ability to discipline such practitioners is necessary for the protection of the citizens of this State and for the public interest, health, welfare, and safety.

### **Definition**

“The practice of medicine across state lines” means:

1. the rendering of a written or otherwise documented medical opinion concerning diagnosis or treatment of a patient within this State by a physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such physician or his or her agent; or



2. the rendering of treatment to a patient within this State by a physician located outside this State as a result of transmission of individual patient data by electronic or other means from within this State to such physician or his or her agent.

### **License Requirement**

No person shall engage in the practice of medicine across state lines in this State, shall hold himself or herself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he or she is licensed to practice medicine across state lines in this State unless he or she is actually so licensed in accordance with the provisions of this article.

### **Issuance of License**

The Board shall issue a special purpose license to practice medicine across state lines upon application for the same from a person holding a full and unrestricted license to practice medicine in any and all states of the United States or its territories in which such individual is licensed, provided there has not been previous disciplinary or other action against the applicant by any state or jurisdiction. In the event of previous disciplinary or other action against the applicant, the Board may, in its discretion, issue a license to practice medicine across state lines if it finds that the previous disciplinary or other action does not indicate that the physician is a potential threat to the public. An individual shall submit an application to the Board on a form provided by the Board and shall remit to the Board a reasonable fee for such license, the amount of the fee to be set by the Board. A license to practice medicine across state lines issued by the Board limits the licensee solely to the practice of medicine across state lines as defined herein. The special purpose license in this State is valid for the term of \_\_\_\_\_ years (to be set by the Board to conform with renewal requirements for full and unrestricted licenses) and is renewable upon receipt of a reasonable fee, as set by the Board, and submission of a renewal application on forms provided by the Board.

### **Effect of License**

The issuance by the Board of a special purpose license to practice medicine across state lines subjects the licensee to the jurisdiction of the Board in all matters set forth in the Medical Practice Act and implementing rules and regulations, including all matters related to discipline. In addition, the licensee agrees by acceptance of such license to produce patient medical records and/or materials as requested by the Board and/or appear before the Board or any of its committees within \_\_\_\_\_ days (to be set by the Board) following receipt of a written notice issued by the Board. Such notice will be issued by the Board pursuant to any complaint or report filed or any complaint initiated by the Board or any of its committees when records and/or materials are deemed relevant to said complaint or report.

Failure of the licensee to appear and/or to produce records or materials as requested, after appropriate notice, allows the Board to suspend or revoke the licensee's special purpose license at its discretion. Notwithstanding any provision of State law to the contrary, such suspension or revocation of such license may be effected prior to a hearing, after appropriate notice and if the Board finds an ongoing and continuous threat to the public. Such action taken by the Board shall be deemed a disciplinary action, for purpose of action by any other state.

### **Patient Medical Records**

Any licensee licensed under the provision of this Act shall comply with all laws, rules and regulations governing the maintenance of patient medical records, including patient confidentiality requirements, regardless of the state where the medical records of any patient within this State are maintained.

### **Exemptions**

A physician who engages in the practice of medicine across state lines in an emergency, as defined by the Board, is not subject to the provisions of this Act.

A physician who engages in the practice of medicine across state lines on an irregular or infrequent basis is not subject to the provisions of this Act. The “irregular or infrequent” practice of medicine across state lines is deemed to occur if such practice occurs less than once a month or involves less than ten patients on an annual basis, or comprises less than one percent (1%) of the physician’s diagnostic or therapeutic practice.

A physician, who engages in the informal practice of medicine across state lines without compensation or expectation of compensation, is not subject to the provisions of this Act. (The practice of medicine across state lines conducted within the parameters of a contractual relationship shall not be considered informal and shall be subject to regulation by the Board.)

### **Sanctions**

Any person who violates the provisions of this Act is subject to criminal prosecution for the unlicensed practice of medicine, and/or injunctive or other action authorized in this State to prohibit or penalize continued practice without a license.

Nothing in this Act shall be interpreted to limit or restrict the Board’s authority to discipline any physician licensed to practice in this State who violates the Medical Practice Act while engaging in the practice of medicine within this or any other State.

---

### **The Ad Hoc Committee on Telemedicine**

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Ad Hoc Committee on Telemedicine  
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## **ATTACHMENT G**

*The Practice of Internet Counseling  
(National Board for Certified Counselors and  
Center for Credentialing and Education)*

# The Practice of Internet Counseling

National Board for Certified Counselors, Inc.  
and  
Center for Credentialing and Education, Inc.  
3 Terrace Way, Suite D  
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This document contains a statement of principles for guiding the evolving practice of Internet counseling. In order to provide a context for these principles, the following definition of Internet counseling, which is one element of technology-assisted distance counseling, is provided. The Internet counseling standards follow the definitions presented below.

## **A Taxonomy for Defining Face-To-Face and Technology-Assisted Distance Counseling**

The delivery of technology-assisted distance counseling continues to grow and evolve. Technology assistance in the form of computer-assisted assessment, computer-assisted information systems, and telephone counseling has been available and widely used for some time. The rapid development and use of the Internet to deliver information and foster communication has resulted in the creation of new forms of counseling. Developments have occurred so rapidly that it is difficult to communicate a common understanding of these new forms of counseling practice.

The purpose of this document is to create standard definitions of technology-assisted distance counseling that can be easily updated in response to evolutions in technology and practice. A definition of traditional face-to-face counseling is also presented to show similarities and differences with respect to various applications of technology in counseling. A taxonomy of forms of counseling is also presented to further clarify how technology relates to counseling practice.

## **Nature of Counseling**

Counseling is the application of mental health, psychological, or human development principles, through cognitive, affective, behavioral or systemic intervention strategies, that address wellness, personal growth, or career development, as well as pathology.

Depending on the needs of the client and the availability of services, counseling may range from a few brief interactions in a short period of time, to numerous interactions over an extended period of time. Brief interventions, such as

classroom discussions, workshop presentations, or assistance in using assessment, information, or instructional resources, may be sufficient to meet individual needs. Or, these brief interventions may lead to longer-term counseling interventions for individuals with more substantial needs. Counseling may be delivered by a single counselor, two counselors working collaboratively, or a single counselor with brief assistance from another counselor who has specialized expertise that is needed by the client.

## Forms of Counseling

Counseling can be delivered in a variety of forms that share the definition presented above. Forms of counseling differ with respect to participants, delivery location, communication medium, and interaction process. Counseling *participants* can be **individuals, couples, or groups**. The *location* for counseling delivery can be **face-to-face or at a distance** with the assistance of technology. The *communication medium* for counseling can be what is **read** from text, what is **heard** from audio, or what is **seen** and heard in person or from video. The *interaction process* for counseling can be **synchronous** or **asynchronous**. Synchronous interaction occurs with little or no gap in time between the responses of the counselor and the client. Asynchronous interaction occurs with a gap in time between the responses of the counselor and the client.

The selection of a specific form of counseling is based on the needs and preferences of the client within the range of services available. Distance counseling supplements face-to-face counseling by providing increased access to counseling on the basis of **necessity** or **convenience**. Barriers, such as being a long distance from counseling services, geographic separation of a couple, or limited physical mobility as a result of having a disability, can make it **necessary** to provide counseling at a distance. Options, such as scheduling counseling sessions outside of traditional service delivery hours or delivering counseling services at a place of residence or employment, can make it more **convenient** to provide counseling at a distance.

*A Taxonomy of Forms of Counseling Practice.* Table 1 presents a taxonomy of currently available forms of counseling practice. This schema is intended to show the relationships among counseling forms.

Table 1

### A Taxonomy of Face-To-Face and Technology-Assisted Distance Counseling

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#### Counseling

- Face-To-Face Counseling
  - Individual Counseling

- Couple Counseling
  - Group Counseling
- Technology-Assisted Distance Counseling
  - Telecounseling
    - Telephone-Based Individual Counseling
    - Telephone-Based Couple Counseling
    - Telephone-Based Group Counseling
  - Internet Counseling
    - E-Mail-Based Individual Counseling
    - Chat-Based Individual Counseling
    - Chat-Based Couple Counseling
    - Chat-Based Group Counseling
    - Video-Based Individual Counseling
    - Video-Based Couple Counseling
    - Video-Based Group Counseling

---

## Definitions

*Counseling* is the application of mental health, psychological, or human development principles, through cognitive, affective, behavioral or systemic intervention strategies, that address wellness, personal growth, or career development, as well as pathology.

*Face-to-face counseling* for individuals, couples, and groups involves synchronous interaction between and among counselors and clients using what is seen and heard in person to communicate.

Technology-assisted distance counseling for individuals, couples, and groups involves the use of the telephone or the computer to enable counselors and clients to communicate at a distance when circumstances make this approach necessary or convenient.

Telecounseling involves synchronous distance interaction among counselors and clients using one-to-one or conferencing features of the telephone to communicate.

Telephone-based individual counseling involves synchronous distance interaction between a counselor and a client using what is heard via audio to communicate.

Telephone-based couple counseling involves synchronous distance interaction among a counselor or counselors and a couple using what is heard via audio to communicate.

Telephone-based group counseling involves synchronous distance interaction among counselors and clients using what are heard via audio to communicate.

Internet counseling involves asynchronous and synchronous distance interaction among counselors and clients using e-mail, chat, and videoconferencing features of the Internet to communicate.

E-mail-based individual Internet counseling involves asynchronous distance interaction between counselor and client using what is read via text to communicate.

Chat-based individual Internet counseling involves synchronous distance interaction between counselor and client using what is read via text to communicate.

Chat-based couple Internet counseling involves synchronous distance interaction among a counselor or counselors and a couple using what is read via text to communicate.

Chat-based group Internet counseling involves synchronous distance interaction among counselors and clients using what are read via text to communicate.

Video-based individual Internet counseling involves synchronous distance interaction between counselor and client using what is seen and heard via video to communicate.

Video-based couple Internet counseling involves synchronous distance interaction among a counselor or counselors and a couple using what is seen and heard via video to communicate.

Video-based group Internet counseling involves synchronous distance interaction among counselors and clients using what is seen and heard via video to communicate.



## **Standards for the Ethical Practice of Internet Counseling**

These standards govern the practice of Internet counseling and are intended for use by counselors, clients, the public, counselor educators, and organizations that examine and deliver Internet counseling. These standards are intended to address practices that are unique to Internet counseling and Internet counselors and do not duplicate principles found in traditional codes of ethics.

These Internet counseling standards of practice are based upon the principles of ethical practice embodied in the NBCC Code of Ethics. Therefore, these standards should be used in conjunction with the most recent version of the NBCC ethical code. Related content in the NBCC Code are indicated in parentheses after each standard.

Recognizing that significant new technology emerges continuously, these standards should be reviewed frequently. It is also recognized that Internet counseling ethics cases should be reviewed in light of delivery systems existing at the moment rather than at the time the standards were adopted.

In addition to following the NBCC® Code of Ethics pertaining to the practice of professional counseling, Internet counselors shall observe the following standards of practice:

### **Internet Counseling Relationship**

1. In situations where it is difficult to verify the identity of the Internet client, steps are taken to address impostor concerns, such as by using code words or numbers.
2. Internet counselors determine if a client is a minor and therefore in need of parental/guardian consent. When parent/guardian consent is required to provide Internet counseling to minors, the identity of the consenting person is verified.
3. As part of the counseling orientation process, the Internet counselor explains to clients the procedures for contacting the Internet counselor when he or she is off-line and, in the case of asynchronous counseling, how often e-mail messages will be checked by the Internet counselor.
4. As part of the counseling orientation process, the Internet counselor explains to clients the possibility of technology failure and discusses alternative modes of communication, if that failure occurs.
5. As part of the counseling orientation process, the Internet counselor explains to clients how to cope with potential misunderstandings when visual cues do not exist.

6. As a part of the counseling orientation process, the Internet counselor collaborates with the Internet client to identify an appropriately trained professional who can provide local assistance, including crisis intervention, if needed. The Internet counselor and Internet client should also collaborate to determine the local crisis hotline telephone number and the local emergency telephone number.
7. The Internet counselor has an obligation, when appropriate, to make clients aware of free public access points to the Internet within the community for accessing Internet counseling or Web-based assessment, information, and instructional resources.
8. Within the limits of readily available technology, Internet counselors have an obligation to make their Web site a barrier-free environment to clients with disabilities.
9. Internet counselors are aware that some clients may communicate in different languages, live in different time zones, and have unique cultural perspectives. Internet counselors are also aware that local conditions and events may impact the client.

### **Confidentiality in Internet Counseling**

10. The Internet counselor informs Internet clients of encryption methods being used to help insure the security of client/counselor/supervisor communications.

Encryption methods should be used whenever possible. If encryption is not made available to clients, clients must be informed of the potential hazards of unsecured communication on the Internet. Hazards may include unauthorized monitoring of transmissions and/or records of Internet counseling sessions.

11. The Internet counselor informs Internet clients if, how, and how long session data are being preserved.

Session data may include Internet counselor/Internet client e-mail, test results, audio/video session recordings, session notes, and counselor/supervisor communications. The likelihood of electronic sessions being preserved is greater because of the ease and decreased costs involved in recording. Thus, its potential use in supervision, research, and legal proceedings increases.

12. Internet counselors follow appropriate procedures regarding the release of information for sharing Internet client information with other electronic sources.

Because of the relative ease with which e-mail messages can be forwarded to formal and casual referral sources, Internet counselors must work to insure the confidentiality of the Internet counseling relationship.

### **Legal Considerations, Licensure, and Certification**

13. Internet counselors review pertinent legal and ethical codes for guidance on the practice of Internet counseling and supervision.

Local, state, provincial, and national statutes as well as codes of professional membership organizations, professional certifying bodies, and state or provincial licensing boards need to be reviewed. Also, as varying state rules and opinions exist on questions pertaining to whether Internet counseling takes place in the Internet counselor's location or the Internet client's location, it is important to review codes in the counselor's home jurisdiction as well as the client's. Internet counselors also consider carefully local customs regarding age of consent and child abuse reporting, and liability insurance policies need to be reviewed to determine if the practice of Internet counseling is a covered activity.

14. The Internet counselor's Web site provides links to websites of all appropriate certification bodies and licensure boards to facilitate consumer protection.

## **ATTACHMENT H**

*Enacted Texas Law Requiring Private Payors to  
Reimburse for Telemedicine Services*

1-1 By: Gray (Senate Sponsor - Sibley) H.B. No.  
2033

1-2 (In the Senate - Received from the House May 2, 1997;

1-3 May 5, 1997, read first time and referred to Committee on  
Economic

1-4 Development; May 16, 1997, reported adversely, with favorable

1-5 Committee Substitute by the following vote: Yeas 8, Nays 0;

1-6 May 16, 1997, sent to printer.)

1-7 COMMITTEE SUBSTITUTE FOR H.B. No. 2033 by:  
Sibley

1-8 A BILL TO BE ENTITLED

1-9 AN ACT

1-10 relating to coverage for services provided through  
telemedicine

1-11 under certain health benefit plans.

1-12 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-13 SECTION 1. Subchapter E, Chapter 21, Insurance Code, is

1-14 amended by adding Article 21.53F to read as follows:

1-15 Art. 21.53F. TELEMEDICINE

1-16 Sec. 1. DEFINITIONS. In this article:

1-17 (1) "Health benefit plan" means a plan described  
by

1-18 Section 2 of this article.

1-19 (2) "Telemedicine" means the use of interactive  
audio,

1-20 video, or other electronic media to deliver health care. The  
term

1-21 includes the use of electronic media for diagnosis,  
consultation,

1-22 treatment, transfer of medical data, and medical education.  
The

1-23 term does not include services performed using a telephone or

1-24 facsimile machine.

1-25                    Sec. 2. SCOPE OF ARTICLE. (a) This article applies  
only to

1-26            a health benefit plan that:

1-27                    (1) provides benefits for medical or surgical  
expenses

1-28            incurred as a result of a health condition, accident, or  
sickness,

1-29            including:

1-30                    (A) an individual, group, blanket, or  
franchise

1-31            insurance policy or insurance agreement, a group hospital  
service

1-32            contract, or an individual or group evidence of coverage that  
is

1-33            offered by:

1-34                    (i) an insurance company;

1-35                    (ii) a group hospital service  
corporation

1-36            operating under Chapter 20 of this code;

1-37                    (iii) a fraternal benefit society

1-38            operating under Chapter 10 of this code;

1-39                    (iv) a stipulated premium insurance

1-40            company operating under Chapter 22 of this code; or

1-41                    (v) a health maintenance organization

1-42            operating under the Texas Health Maintenance Organization Act

1-43            (Chapter 20A, Vernon's Texas Insurance Code); or

1-44                    (B) to the extent permitted by the Employee

1-45            Retirement Income Security Act of 1974 (29 U.S.C. Section 1001  
et

1-46            seq.), a health benefit plan that is offered by a multiple  
employer

1-47            welfare arrangement as defined by Section 3, Employee  
Retirement

1-48 Income Security Act of 1974 (29 U.S.C. Section 1002) or  
another

1-49 analogous benefit arrangement; or

1-50 (2) is offered by an approved nonprofit health

1-51 corporation that is certified under Section 5.01(a), Medical

1-52 Practice Act (Article 4495b, Vernon's Texas Civil Statutes),  
and

1-53 that holds a certificate of authority issued by the  
commissioner

1-54 under Article 21.52F of this code.

1-55 (b) This article does not apply to:

1-56 (1) a plan that provides coverage:

1-57 (A) only for a specified disease;

1-58 (B) only for accidental death or  
dismemberment;

1-59 (C) for wages or payments in lieu of wages  
for a

1-60 period during which an employee is absent from work because of

1-61 sickness or injury; or

1-62 (D) as a supplement to liability insurance;

1-63 (2) a small employer health benefit plan written  
under

1-64 Chapter 26 of this code;

2-1 (3) a Medicare supplemental policy as defined by

2-2 Section 1882(g)(1), Social Security Act (42 U.S.C. Section  
1395ss);

2-3 (4) workers' compensation insurance coverage;

2-4 (5) medical payment insurance issued as part of a

2-5 motor vehicle insurance policy; or

2-6 (6) a long-term care policy, including a nursing  
home

2-7 fixed indemnity policy, unless the commissioner determines  
that the

2-8 policy provides benefit coverage so comprehensive that the  
policy

2-9 is a health benefit plan as described by Subsection (a) of  
this

2-10 section.

2-11 Sec. 3. COVERAGE FOR TELEMEDICINE SERVICES. (a) A  
health

2-12 benefit plan may not exclude a service from coverage under the  
plan

2-13 solely because the service is provided through telemedicine  
and not

2-14 provided through a face-to-face consultation.

2-15 (b) Benefits for a service provided through  
telemedicine

2-16 required under this article may be made subject to a  
deductible,

2-17 copayment, or coinsurance requirement. A deductible,  
copayment, or

2-18 coinsurance applicable to a particular service provided  
through

2-19 telemedicine may not exceed the deductible, copayment, or

2-20 coinsurance required by the health benefit plan for the same

2-21 service provided through a face-to-face consultation.

2-22 Sec. 4. INFORMED CONSENT. A treating physician or  
other

2-23 health care provider who provides or facilitates the use of

2-24 telemedicine shall ensure that the informed consent of the  
patient,

2-25 or another appropriate person with authority to make health  
care

2-26 treatment decisions for the patient, is obtained before  
services

2-27 are provided through telemedicine.

2-28 Sec. 5. CONFIDENTIALITY. A treating physician or other

2-29 health care provider who provides or facilitates the use of



2-30 telemedicine shall ensure that the confidentiality of the  
patient's

2-31 medical information is maintained as required by Section 5.08,

2-32 Medical Practice Act (Article 4495b, Vernon's Texas Civil

2-33 Statutes), or other applicable law.

2-34 Sec. 6. RULES. (a) Subject to Subsection (b) of this

2-35 section, the commissioner may adopt rules as necessary to  
implement

2-36 this article.

2-37 (b) The Texas State Board of Medical Examiners, in

2-38 consultation with the commissioner, as appropriate, may adopt  
rules

2-39 as necessary to:

2-40 (1) ensure that appropriate care is provided to

2-41 patients who receive services that are provided through

2-42 telemedicine; and

2-43 (2) prevent abuse and fraud through use of

2-44 telemedicine services, including rules relating to filing of  
claims

2-45 and records required to be maintained in connection with

2-46 telemedicine.

2-47 SECTION 2. This Act takes effect September 1, 1997, and

2-48 applies only to a health benefit plan that is delivered,  
issued for

2-49 delivery, or renewed on or after January 1, 1998. A health  
benefit

2-50 plan that is delivered, issued for delivery, or renewed before

2-51 January 1, 1998, is governed by the law as it existed  
immediately

2-52 before the effective date of this Act, and that law is  
continued in

2-53 effect for this purpose.

2-54 SECTION 3. The importance of this legislation and the

2-55 crowded condition of the calendars in both houses create an  
2-56 emergency and an imperative public necessity that the  
2-57 constitutional rule requiring bills to be read on three  
several  
2-58 days in each house be suspended, and this rule is hereby  
suspended.  
2-59 \* \* \* \* \*

## **ATTACHMENT I**

*eRX National ePrescribing Patient Safety Initiative:  
Legislative Fact Sheet of State Laws, Proposed Legislation, and Executive Orders  
Related to Electronic Prescribing and Medication Error Reduction*



## Legislation Fact Sheet

Electronic Prescribing/Medication Error Reduction State Legislation, including laws, proposed legislation, and executive order (2003-2006)

### California

AB 225 -- Directs the Secretary of State Health and Human Services Agency to promulgate regulations to provide hardware and software to healthcare providers for the purpose of eprescribing without violating anti-kickback laws.  
(signed by the governor 10.06)

### Colorado

HB 03-1063 -- Allows the patient to request the prescription label to list the purpose or symptoms for which the prescription is written. In the case of anabolic steroids, it is mandatory. Also requires the prescriber to notify the patient of this option but not grounds for discipline if they do not.  
(Filed 1/8/03; passed House 1/20/03; passed Senate 3/10/03; **signed into law by governor** 3/25/03)

### Delaware

HB 33 -- Allows a pharmacist to put the symptom or purpose for the drug being prescribed on the drug container label, but only if a practitioner indicates that the patient or their authorized representative requests information on the label.  
(Filed 1/25/05; passed House 6/21/05; passed Senate in final form 6/30/05; **signed into law by governor** 7/7/05)

SB 48 -- Would require prescriptions to be written legibly so that pharmacists filling them can do so accurately and thereby avoid potential harm to the consumer.  
(Filed 3/22/05; passed Senate 6/15/05; passed House 6/28/05; **signed into law by governor** 7/12/05)

### Florida

Chapter 2006-271 signed into law by governor on June 22, 2006; allows for the development and regulation of electronic prescribing practices.

Chapter 2003-41 -- Requires that written drug prescriptions "must be legibly printed or typed" to assure they can be understood by pharmacists. Effective date July 1, 2003.  
(Filed 3/4/03; passed Senate 4/30/03; passed House 5/1/03; **signed into law by governor** 5/23/03 as Chapter 2003-41)

### Georgia

SB 397 -- Would require that electronically transmitted prescription drug orders may only be transmitted by the prescribing practitioner and must be transmitted directly to the patient's pharmacy of choice with no access by intervening persons. For the purposes of this bill, electronically transmitted prescription drug orders would be considered

confidential.

*(Filed and referred to committee 1/10/06; did not pass by end of regular session)*

### **Idaho**

SB 1412 -- Provides procedures for long-term care and assisted living facilities to fax and verbally send prescription drug orders to a pharmacy when it has been so ordered by a doctor; also allows for electronic transmission of prescriptions.

*(Filed 2/20/06; passed Senate 33y-0n, 3/06/06; passed House 66y-0n, 3/24/06; **signed into law by governor** as Ch. 290, 3/31/06)*

37-3725 -- Requires prescriptions to be legible by a pharmacist and provides for disciplinary measures by the Board of Pharmacy if it is not. No record of disposition.

### **Illinois**

SB 2253 -- Amends the Pharmacy Practice Act, by adding the activities of "preparation, computer entry and verification of medication orders, medical devices and prescriptions" as steps regulated under pharmaceutical dispensing.

*(Passed Senate 3/25/04; passed House 5/26/04; **signed into law by governor** as Public Act 93-1075, 1/18/05)*

Executive Order #8 – To encourage all medical providers to utilize e-prescribing programs by 2011; to evaluate the areas within Illinois in need of enhanced technology to support e-prescribing programs; to determine the types of technology needed to implement the e-prescribing program; to coordinate with the Illinois Department of Financial and Professional Regulation and the Department of Healthcare and Family Services to draft and issue recommended medication practices such as prescribing, dispensing, and maintenance to all health care providers; to expand the Department's nursing home database to include information such as staffing ratios, medication distribution, on-site services, and citations issued against each facility, enabling consumers to make well-informed decisions; to implement and expand the State's efforts at health care provider information transparency, such as the Hospital Report Card, the Consumer Guide to Health, and similar efforts to ensure that health care consumers and purchasers may make informed choices regarding the quality and cost effectiveness of medical care; to implement the Illinois Adverse Health Care Events Reporting Law.

*(Issued by the governor on July 13, 2006; effective immediately)*

### **Iowa**

HF 2087 -- Would require that electronic prescription drug orders issued by practitioners and filled by a pharmacy comply with the rules adopted by the Board of Pharmacy Examiners specifically for such orders. The rules are to be consistent with federal law and regulations relating to electronic prescriptions, including the standards established for the Medicare electronic prescription drug program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

*(Filed and referred to committee 1/19/06; did not pass by end of regular session)*

HF 722 -- Directs Board to establish and maintain an electronic drug database used to monitor the misuse, abuse and diversion of controlled substances and other drugs; provides for the electronic collection and dissemination of information; allows the Board to contract with a third-party/private vendor to administer the electronic drug database.

*(Filed 3/22/05; passed Assembly 98y-0n, 3/22/05; passed Senate, 48y-0n, 3/29/06; **signed into law by governor** 5/31/06)*

### **Kentucky**

HB 729 -- Would establish a real time electronic data collection system for controlled substances, Medicaid prescriptions and Medicare Part D prescriptions, and would require those dispensing prescriptions to report data electronically in real time when prescribing and dispensing the prescribed drug.

*(Filed and referred to committee 2/27/06)*

### **Maryland**

SB333 -- Would establish and maintain a Prescription Drug Monitoring Program within the Department of Health and Mental Hygiene in order to assist health care professionals and law enforcement agents in the identification, treatment and prevention of prescription drug abuse.

*(Filed and referred to committee 1/27/06; passed Senate 47y-0n, 3/26/06; passed House 138y-0n, 4/6/06; **vetoed by governor** 5/26/06)*

HB 433 -- Requires prescribers to print or type written prescriptions in a legible manner.

*(Filed 1/29/04; passed House 3/12/04, passed Senate 4/4/04; **signed into law by governor** as Chapter 503, 5/26/04)*

### **Massachusetts**

S 1276 -- Would convene a task force to study methods for reducing medication and prescription errors, including recommendations on prescription legibility, drug labeling and packaging, medication error reporting plans, automated drug ordering systems, and patient education.

*(Filed 1/26/05; hearing 9/21/05; favorable committee report 3/28/06)*

### **Michigan**

HB 4434 -- Allows a licensed pharmacy to perform "centralized prescription processing services," or to outsource those services to another licensed pharmacy, if certain conditions are satisfied. Would require that pharmacies share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to prepare a prescription drug order. Would require that each prescription drug dispensed under such a system would have to bear a label containing an identifiable code providing a complete audit trail of the preparation and dispensing of the drug and patient care activities.

*(Filed 3/15/05; HB 4434 passed House 104y-0n, 4/21/05; passed Senate 37y-0n, 5/12/05; **signed into law by governor** as Public Act 72, 7/19/05)*

### **Missouri**

SB 835 -- Would require licensed practitioners to issue all written prescriptions. The prescriptions shall be legibly printed or typed, dated with the month written in textual letters and signed by the prescribing practitioner on the day issued. The prescriptions shall also contain the name of the prescribing practitioner, the name, strength and quantity of the prescribed drug, and directions for using the drug.

*(Filed and referred to committee 1/10/06; did not pass by end of 2006 regular session)*

### **Montana**

HB 254 -- Establishes a civil penalty for not writing legible prescriptions.

*(Filed 1/27/05; passed House 1/27/05; passed Senate 4/12/05; **signed into law by governor** 4/28/05)*

### **New Hampshire**

Governor announces an effort on Oct. 19 intended to bring all of the state's doctors e-prescribing capabilities by October, 2007. Lynch is emphasizing the [safety and cost benefits](#) of e-prescribing, which Institute of Medicine research has shown to reduce prescribing errors. The plan, which is designed to bring all other clinicians online by October 2008, is part of a larger pay-for-performance program backed by Lynch's Citizens Health Initiative. The CHI is working with the state's health plans to devise P4P incentives, some of which will reward use of e-prescribing and EMRs. The group is also working to promote the development of a statewide health information network.

### **New Jersey**

A 2718 -- Would require that pharmacists provide additional prescription drug information, notifying consumers, when a generic drug product is dispensed, about the characteristics of that drug product, other than its active ingredient, which differ from the brand-name drug product for which it is being substituted and may be important in the therapy of a particular patient.

*(Filed 5/6/04; carried over to 2005 session & held in committee 10/05)*

### **New York**

The governor announced Oct. 5, 2006 that the state received permission announced from the federal government to allow the state to use federal money for the state's health care reform initiatives, including expanded use of e-prescribing.

SB 6498 -- Would require prescriptions to be typewritten, electronically printed or handwritten in ink or indelible pencil in a legible manner; requires that handwritten prescriptions shall only be written in print letters; prohibits the use of script letters in handwritten prescriptions.

*(Filed and sent to committee 3/16/04; did not pass by end of session 12/04; refiled for 2005-06 as [A 4090](#), [A 4437](#) & [S 2231](#) )*

### **Oklahoma**

HB 2842 -- Legislation created the Oklahoma Medicaid Reform Act of 2006, directing the Oklahoma Health Care Authority to design and implement an e-prescribing pilot program. A report shall be submitted within 18 months of an unspecified start date.

*(Signed by the governor on June 9, 2006)*

SB 614 -- Would clarify language and require placement of the symptom for which a drug is prescribed on the prescription label under specified conditions.

*(Filed 3/10/05; passed Senate; passed House, did not pass conference committee 5/27/05\*)*

### **Rhode Island**

SB2359 -- Would require pharmacies to provide a list of twenty (20) prescribed health maintenance drugs in electronic format to the Department of Health with current selling prices. The list would be posted on a Department of Health web site and would be accessible to the general public.

*(Filed and referred to committee 2/7/06; held for further study 3/22/06; did not pass by end of 2006 regular session)*

## **South Carolina**

HB3803 -- Would enact the South Carolina Prescription Monitoring Act authorizing the Bureau of Drug Control to establish a program to monitor the prescribing and dispensing of schedule II-V controlled substances and to provide the manner and procedures under which dispensers are to provide such information.

*(Filed and referred to committee 3/29/05; passed House 5/13/05; passed Senate 5/31/06; House concurred 6/1/06; **vetoed by governor** 6/13/06; **became law by veto override** as Act 396, 6/14/06)*

## **Tennessee**

Ch. 564 -- Would specify that current law permitting a pharmacist to dispense the least expensive generic equivalent of a drug, or a generic equivalent covered by the patient's drug plan, in cases where the prescriber has not noted medical necessity of the brand name prescribed would not prohibit a pharmacist from complying with the request of a patient with a valid prescription order to obtain a brand name drug or drug product if the patient has prescription drug coverage under a prescription benefit plan and agrees to pay the additional cost, if any, of the brand name drug. If the patient does not have a prescription benefit plan, or the patient's plan does not provide coverage for the brand name drug, then the patient could receive the brand name drug upon agreement to pay the entire cost of the drug; would also provide requirements for electronic prescriptions.

*(HB 3065 filed and referred to committee 2/16/06; passed House 97y-0n, 3/27/06; passed Senate 30y-0n, 4/10/06; **signed into law by governor** as Ch. 564, 4/24/06) (SB 3070 filed and referred to committee 2/16/06; combined with HB 3065, 4/10/06)*

Chapter 678 -- Creates the "Medication Error Reduction Act" for a uniform standard format, requiring written prescription orders to be legible and comprehensible to a pharmacist; would limit the liability of pharmacists for delay incurred when clarifying a prescription that the pharmacist cannot understand.

*(Filed 1/04; SB 2162 **passed Senate** 3/24/04; **passed House** 4/29/04; **signed by governor** as Chapter 678, 5/18/04)*

Chapter 12 -- Makes clarifying changes to the requirement that prescriptions written by various health care practitioners drug must be legibly handwritten or typed or computer generated so that it is comprehensible by the pharmacist.

*(Filed 2/3/05; SB 470 passed Senate 3/2/05; passed House 3/14/05; **signed into law by governor** as Chapter 12, 4/4/05)*

## **Vermont**

Act 235 -- Would establish a prescription drug monitoring program to detect and prevent substance abuse, and support the legitimate medical use of controlled substances.

*(Filed and referred to committee 1/14/05. 2/10/05; carried over; H 45 did not pass by end of 2006 regular session)*

*(S 90 **passed Senate** 1/13/06; **passed House** 5/3/06; **signed into law by governor** as Act 235, 5/31/06)*

## **Washington**

HB 2798 -- Establishes prescription legibility requirements so they are readable by a pharmacist which reduces medication errors.

*(Filed 2/1/00; passed House 2/9/00 ; passed Senate 3/1/00; **signed into law by governor** as Chapter 8, 3/17/00)*



SB 1780 -- Would require improved legibility of prescriptions.

*(Filed 2/4/05; held in committee; did not pass by end of regular session 4/24/05)*

### **Wisconsin**

AB 689 -- Would require that prescription drug labels specify the symptom or purpose for which the drug is being prescribed if the patient wants the symptom or purpose to appear on the label. The practitioner who prescribes the drug must ask the patient if the patient wants the symptom or purpose to appear on the label. If the patient wants that information on the label, the practitioner must add that information to the prescription order and the pharmacist must include that information on the prescription drug label.

*(Filed and sent to committee 12/5/03; did not pass by end of session)*

### **Wyoming**

The Wyoming Health Information Organization (WyHIO) is a nonprofit corporation charged with a number of tasks, including a pilot eprescribing program among Wyoming hospitals as a future project.

## **ATTACHMENT J**

*Report on Task Force on Internet Pharmacies and Prescribing  
(Michigan Department of Consumer & Industry Services  
Bureau of Health Services)*

MICHIGAN DEPARTMENT OF CONSUMER &  
INDUSTRY SERVICES  
BUREAU OF HEALTH SERVICES

**REPORT ON TASK  
FORCE ON INTERNET  
PHARMACIES AND  
PRESCRIBING**

JUNE 5, 2001

## TASK FORCE ON INTERNET PHARMACIES AND PRESCRIBING

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Michigan State Medical Society

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Michigan Board of Pharmacy

Consumer & Industry Services

Michigan Board of Osteopathic  
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Michigan Board of Medicine

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## REPORT ON TASK FORCE ON INTERNET PHARMACIES AND PRESCRIBING

### EXECUTIVE SUMMARY

In January 2000 the Director of the Michigan Department of Consumer & Industry Services convened a task force to examine the issues associated with the practice of prescribing and dispensing prescription medication over the Internet. The task force was charged with the following tasks:

- Review current rules and statutes which potentially affect Internet prescribing and health care, including mail order pharmacies;
- Review Federal regulations and guidelines;
- Review positions, activities, and regulations of other states;
- Discuss security and privacy issues; and
- Make recommendations for administrative rule and/or statutory changes to address health care on the Internet and its regulation in Michigan to the Department of Consumer & Industry Services.

The task force identified a number of problems associated with the purchase of pharmaceutical products over the Internet from unregulated pharmacy websites. These problems include the inability to assure that a legitimate prescriber-patient relationship exists, lack of opportunity for patient education regarding appropriate use of medications, potential for violation of patient privacy, and the inability to appropriately document the prescribing and dispensing of medication.

The task force recognized that in order to address the utilization of new technologies, such as the Internet, in the delivery of health care, a number of statutory and rule changes would need to be pursued. Recommendations for statutory changes relative to utilizing the Internet as part of the practice of pharmacy will impact Part 177 of the Michigan Public Health Code.

Recommendations offered by the task force include the following:

- Amend the definitions of dispensing, pharmacy, prescriber, prescription, and substitution to reflect the impact of Internet pharmacy practices.
- Define the nature of the prescriber-patient relationship, require verification of the prescriptions validity, the identity of the patient and the identity of the provider.
- Adopt standards such as the Verified Internet Pharmacy Practice Site (VIPPS) criteria for identifying legitimate Internet pharmacies.

- Eliminate the current restriction on mail order in the State of Michigan.
- Establish licensure requirements for Internet and mail order pharmacies.
- Provide requirements to assure the confidentiality of health information communicated via the Internet.

MICHIGAN DEPARTMENT OF CONSUMER & INDUSTRY SERVICES  
BUREAU OF HEALTH SERVICES

REPORT ON TASK FORCE ON INTERNET  
PHARMACIES AND PRESCRIBING

**II. BACKGROUND**

The Internet has become increasingly integrated into the health care delivery system in recent years. Correspondingly, sales of pharmaceutical products over the Internet through both foreign and domestic websites have increased exponentially since on-line pharmacy sites were introduced approximately a year and a half ago. With the number of sites increasing dramatically, consumer safety has become a concern of the stakeholders involved with the prescribing and dispensing of prescription drugs. The medical and pharmacy professional associations, federal and state government agencies, and pharmaceutical manufacturers have identified the need to address regulatory issues associated with the practice of prescribing and dispensing prescription medication over the Internet. In January 2000 the Director of the Michigan Department of Consumer and Industry Services convened a task force to examine the issues associated with Internet practices.

To ensure proper regulation of Internet pharmacies and prescribing without inhibiting the benefits to the citizens of Michigan that are inherent in the ability to utilize the Internet, the task force was charged with the following tasks:

- Review current rules and statutes which potentially affect Internet prescribing and health care, including mail order pharmacies;
- Review Federal guidelines and regulations;
- Review positions, activities and regulations of other states;
- Discuss security and privacy issues; and
- Make recommendations for administrative rule and/or statutory changes to address health care on the Internet and its regulation in Michigan to the Department of Consumer and Industry Services.

From January 2000 to January 2001 the task force met a total of six times. (Reference Attachment A for a list of meeting dates.) A draft report outlining the major issues associated with Internet prescribing and Internet pharmacies, as well as proposed recommendations, went to public hearing on September 20, 2000. (Attachment B includes a copy of the transcript of the public hearing.)



## II. ISSUES

Unlike the traditional brick and mortar community pharmacies that are controlled by the respective state boards of pharmacy and federal law, on-line pharmacy websites have proven difficult to regulate because of the nature of the Internet. Sites can instantaneously appear on-line, pursue sales and distribute pharmaceutical products, and then change their name or virtually disappear overnight. Domestically owned Internet pharmacies have been difficult to regulate because there has been no common regulatory entity controlling their activities in this country, and foreign/off-shore websites complicate the picture even further. Without a regulatory body providing oversight, these websites have been able to sell pharmaceutical products without threat of penalty if laws governing prescribing and dispensing are broken.

There is concern about the types of drugs being purchased over the Internet and in particular, the sale of "lifestyle" drugs such as Viagra, Xenical, Propecia, Retin A, and Prozac. Convenience and anonymity are frequently the reasons consumers choose the Internet to purchase these and other drugs because nothing more is required than a click of a mouse and a credit card number. While there are legitimate on-line pharmacies adhering to the laws and ethics governing the practice of medicine and pharmacy, there are on-line pharmacies, in conjunction with their on-line provider consultants, whose practices are not legal or ethical. Instead of requiring a valid prescription from the consumer's provider prior to dispensing a particular medication, some pharmacy sites dispense medication based only on the customer's request for the drugs. Others require that consumers complete an on-line health history questionnaire prior to dispensing medication, but nothing is done to confirm the information provided. Fraudulent sites may offer an on-line consultation with a "cyber" provider but no opportunity for a physical examination performed by the provider prescribing the medication. There are numerous documented and anecdotal stories relating incidents in which medications have been approved for dispensing from on-line pharmacies when the consumer's health history is contradictory to such a prescription.

The task force also identified the following problems associated with the purchase of pharmaceutical products over the Internet from unregulated pharmacy websites:

- Inability to assure that a provider has performed a physical examination or has an established relationship with a patient for whom s/he is going to prescribe medication;
- Lack of face-to-face communication between a patient and a pharmacist regarding the appropriate use of medications and possible drug interactions;
- Inability to establish a collaborative relationship between the prescriber, patient, and pharmacist.
- Potential for violation of a patients' right to privacy;

- Lack of a confirmed diagnosis prior to prescribing and dispensing medication;
- Absence of an appropriate record-keeping system to document the prescribing and dispensing of medication, including the lack of a written prescription validating a legitimate encounter between the patient and the provider.

### III. DISCUSSION

The task force recognized that as presently written the language contained in the Michigan Public Health Code does not address the verification of patient identity, the need for an established diagnosis, and the need for a provider to be available for follow-up or emergency care. (Reference Attachment C for definitions.) Given the lack of appropriate language, the task force identified the need to define the prescriber-patient relationship. In trying to draft a definition, the task force felt it was important that the definition be applicable in all domains in which a prescriber or pharmacy might be located. There is concern, however, that enforcing regulations associated with such a definition may be arduous when the scope of the Internet is considered.

In an effort to aid consumers in differentiating between legitimate on-line pharmacy websites and those that pursue fraudulent activities, the National Association of Boards of Pharmacies (NABP) developed certification criteria for pharmacy websites. The Verified Internet Pharmacy Practice Sites (VIPPS) criteria were developed to educate consumers about the qualifications of on-line pharmacies and to aid state pharmacy boards in regulating the on-line sites.

The NABP differentiates between pharmacy-based sites and prescribing-based sites. Pharmacy-based sites are defined by the NABP as those that are licensed or registered by state boards of pharmacy and do not offer prescribing services. Prescribing-based sites are those who offer prescribing services based on completion of an on-line health history or an on-line consultation with a prescriber who may be physically located elsewhere. There may be no legitimate prescriber-patient relationship established in these situations.

Acknowledging the differences in on-line pharmacies and their inability to meet state licensing board requirements for prescribing and dispensing, the NABP determined that based on VIPPS criteria those sites would be required to receive certification and adhere to the licensure requirements in all states in which the pharmacy practices. Websites that meet the VIPPS criteria are permitted to display the VIPPS symbol on their sites identifying them as having been certified by the NABP and should be considered legitimate for safe purchases. The Michigan Department of Consumer & Industry Services Internet task force agreed to adopt the principles outlined by VIPPS for the practice of pharmacy over the Internet as a guide in establishing new regulations in Michigan. The VIPPS certification criteria are attached. (See Attachment D.)

In addition to adopting VIPPS criteria, the task force considered expansion of the ability of Michigan pharmacies to dispense controlled substances over state lines so that Michigan pharmacies would be capable of competing with mail-order pharmacies. The task force also discussed possible changes in the law that would permit use of an official electronic prescription form for Schedule II medications if Drug Enforcement Administration regulations change in the future.

With Internet pharmacies, it is possible the physical location of the dispensing pharmacy may be geographically separate from the site from which the website originates. A change in 333.17743 may be required to address the relationship between the Internet site and the location from where medications are dispensed. The consumer may believe the physical location of the pharmacy is the same as that of the website, when in reality, the actual pharmacy that serves a particular website may be located elsewhere. The task force determined there should be a mechanism by which a pharmacy doing business via a website can be clearly identified by its Internet address. Each pharmacy website should be licensed to practice in the State of Michigan. The task force noted that there are umbrella websites that contract with various pharmacies to provide individual pharmacies with access to a website so that they can conduct business over the Internet. The task force expressed its intent to have all pharmacies affiliated with an umbrella website licensed and identified with Internet sites that do business in the State of Michigan.

The task force determined that the existing mail-order restriction on pharmacies in Michigan should be removed from law. The restriction prevents Michigan pharmacists from receiving and sending out prescriptions by mail. The change recommended by the task force would help Michigan pharmacies compete with out-of-state mail-order pharmacies. Mail order programs have eased some of the difficulties patients have experienced gaining access to prescriptions. Access, in this case, could be financial access (the ability to afford medications) or physical access (being sufficiently mobile to be able to obtain medications). Major employers, labor organizations, and other constituency groups representing the general public, report that mail order pharmacies have been a useful mechanism in holding down prescription costs. The task force also addressed potential problems related to the delivery of medication when no personal contact is made with the person for whom the medication is intended.

Confidentiality of health information is an area of concern which needs to be addressed through statutory language. One area of concern is the passage of the federal Health Insurance Portability and Accountability Act (HIPAA) and the impact on the management of health information by individuals and entities identified as "health care providers" in the federal regulations. Under the definition of "health care providers", pharmacies are specifically identified as one of the categories of providers having to comply with the requirements of HIPAA. Two of the areas that are germane to the work of the task force include the Standards for Privacy of Individually Identifiable Health Information and the Standards for Electronic Signatures. Pharmacies, including those doing business on the

Internet, will be required to implement policies and procedures to assure that the requirements for privacy are met. In addition to addressing the impact of HIPAA, there remain other concerns about protecting the privacy of both health and financial information that is exchanged over the Internet in the process of dispensing prescriptions to the patient. There is also a concern about the delivery of pharmaceuticals through the mail when receipt of the medication might be by someone other than the patient, i.e. a family member accepts delivery of the package, who then has potential access to information about the patients' health status.

#### IV. RECOMMENDATIONS

The task force recognized that in order to address the utilization of new technologies, such as Internet communication, in the delivery of health care, a number of statutory and rule changes would need to be pursued. Recommendations for statutory changes relative to utilizing the Internet as part of the practice of pharmacy will impact Part 177 of the Public Health Code.

- Definitions in Sections 333.17701 through 333.17709 will need to be modified to address the impact of the Internet on the definitions for dispensing, pharmacy, prescriber, prescription, and substitution.
- Statutory language will need to be included that identifies the essential elements of a prescriber-patient relationship including but not limited to requirements for a valid prescription and a patient's health history.
- Consumers need to know they are dealing with a legitimate "on-line" pharmacy. To aid consumers, legislation will be needed to establish a standard for Internet pharmacies. Acknowledging by statute the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites (VIPPS) criteria or a similar verification process with substantially equivalent criteria would be an appropriate approach.
- New language will be needed to allow controlled substance prescriptions to be filled from any state through mail order pharmacies. There will also be numerous revisions to existing sections of the Michigan Public Health Code in support of this change.
- Mail order restrictions would also have to be removed to allow Michigan pharmacies to compete with out of state pharmacies. With the removal of the restriction, the task force recommends language to address the appropriate delivery and communications when no personal contact is involved with medication dispensing and delivery.

- The task force identified issues related to confidentiality that would need to be addressed including protecting the privacy of health information communicated over the Internet, the delivery of pharmaceuticals to an individual by mail order that may be received by an individual other than the patient and the impact of the Health Insurance Portability and Accountability Act.

Those sections of the Michigan Public Health Code that will need to be changed to address issues related to Internet pharmacy practices, as well as areas requiring new language, are summarized in the following table:

**TABLE I**  
**PROPOSED LEGISLATIVE CHANGES**

SECTION	RECOMMENDED CHANGE	RATIONALE
333.7333	Change to allow other than land border filling of Schedule II prescriptions.	Current language provides for an exception to the requirement that an official prescription form be used for Schedule II prescriptions for land border practitioners. This language would need to be expanded to include other out-of-state pharmacies (mail order). If not expanded, out-of-state mail order pharmacies, other than those bordering Michigan, would be unable to fill Schedule II prescriptions.
333.7334	Add wording to require the out-of-state pharmacy who fills an official form to send a copy back to the state so we can take the form number out of the system and record the prescription.	The Official Prescription Program (OPP) accounts for all prescription forms which are issued. If out-of-state pharmacies are provided with a supply of forms, the OPP will need a mechanism for reconciling the use of the form. NOTE: This might not be necessary if language regarding land border pharmacies is expanded to include all out-of-state mail order pharmacies.
333.7405	Change to allow other than land border dispensing of controlled substance prescriptions.	Current language prohibits the dispensing of a prescription for controlled substances that is written and signed by a physician prescriber who is licensed to practice in a state other than Michigan, except for those written by prescribers in land border states. This language would need to be expanded to include other states in order for mail order pharmacies to dispense controlled substance prescriptions.

333.17705(3)	Add definition for nonresident pharmacy.	The definition of "license" needs to be expanded to recognize out-of-state pharmacies (Internet and mail orders) as entities that can be licensed in Michigan.
333.17707	Change the definition of "pharmacy" as to what is licensed, the actual location of the dispensing website or both.	The current definition addresses the physical structure of the pharmacy (the "building"). With Internet pharmacies, the website through which a patient obtains their medication may not be the physical location where dispensing occurs. Language is needed to clarify whether it is the dispensing location that is the "pharmacy", the website that is the "pharmacy" or both.
333.17722	Add an addition Board duty to provide for out-of-state license.	Often in mail order or Internet purchases the prescription is received at one location and dispensed from another location
333.17741	Address access issues for out-of-state locations.	Other states allow access to the pharmacy when a pharmacist is not physically present which is inconsistent with Michigan statute.
333.17743	Add a requirement under this section or elsewhere to require a license in the state where located.	Currently out-of-state pharmacies (Internet/mail order) are not allowed to do business in Michigan. Language will have to be added to the Public Health Code which requires the pharmacy to be licensed in order to do business in Michigan.
333.17748	Add another entity to include the Internet pharmacy and/or mail order pharmacy.	Section 17748 identifies the entities required to have a license to do business in Michigan. The language would need to be amended to include Internet and mail order pharmacies in order to allow business to be conducted.

333.17751	Add language to address the Internet pharmacy.	Language would need to be added providing for the electronic transmission of a prescription as an "equivalent record of an original prescription." The section would also need to be amended to allow for the dispensing of controlled substances consistent with the other changes in language recommended.
333.17752	Add language for confidentiality of prescriptions as well as other patient records generated when Internet/mail order pharmacy is used, i.e. who can access, including how the confidentiality is to be assured.	Because confidential patient information will be transmitted via electronic means and subject to potential breaches by people inappropriately accessing data bases through the Internet, additional safeguards need to be provided to protect the rights of patients with regard to the privacy of their health information. In addition, new federal regulations require additional safeguards for health information being transmitted by electronic means.
333.17755	Add provision for addressing conflicts that arise between states.	Generic selection laws vary state by state so there will be occasions when the state in which the prescription is written will handle generic selection differently than the state in which the prescription is being dispensed.
333.17757	Add provision that requires the consumer to be informed of prescription prices prior to purchase.	The consumer has a right to obtain price information so that he or she can make an informed decision before ordering the medication by Internet or mail order.
333.17763	Add language to remove the mail order restriction.	Removal of this restriction would allow Michigan pharmacies equal access to the mail order industry.
333.17768	Expand section on accountability of the pharmacy to include out-of-state pharmacies (Internet, mail order).	This section addresses grounds for discipline and identifies the entities that the section applies to. Out-of-state pharmacies, whether Internet or mail order, would be held to the same standards.



NEW	Language needs to be added to require licensure in the state of consumer residence and proof of licensure to obtain an Internet/mail-order pharmacy license in the State of Michigan.	Licensure in the state of Michigan is required in order for the Department of Consumer & Industry Services to be able to regulate the practice of Internet/mail order pharmacies, enforce provisions of the Public Health Code, and more importantly, protect the public.
NEW	Add language that includes requirements for verification of prescription validity, patient identity and provider identity.	Fundamental to the dispensing of a prescription is the need to know that a provider has an established relationship with a patient for whom s/he is going to prescribe medication. With Internet pharmacies, most of the traditional methods associated with doing business are not available, i.e face-to-face communication between a pharmacist and a patient, the inability to establish a relationship between the prescriber, patient and the pharmacies, and the lack of a written prescription validating a legitimate encounter between a patient and a provider. In the absence of those protections, alternatives have to be identified and incorporated into statute.
NEW	Add a statutory requirement for patient counseling by the dispensing pharmacist.	With Internet and mail order pharmacies, traditional methods of doing business aren't available. This included the opportunity for a face-to-face communication between a pharmacist and a patient during which a patient a pharmacist can discuss the appropriate use of medications and possible drug interactions. the inability to establish a relationship. Statutory language needs to include minimum standards for patient counseling to assure that the patient has access to the appropriate information so they can effectively manage their medication.

NEW	Add language which requires the reporting of medication errors.	This language is needed in order to support enforcement of the Public Health Code and regulation of out-of-state pharmacies.
NEW	Include language which requires the maintenance of records and outlines the minimum requirements.	Pharmacies have to be able to document the basis under which they dispensed a medication. Because written documents, such as the prescription, are not going to be routine when part of an Internet or mail order transaction, pharmacies need to be provided with standards which describe the type of documents that must be maintained in order to assure that the provisions of the Public Health Code are met.
NEW	Add language which defines emergency medication situations and describes how delays in delivery must be handled.	In the case of an Internet pharmacy or a mail order pharmacy, the physical location of the pharmacy may be a significant distance
NEW	Add language requiring that the United States Pharmacopoeia standards be followed during storage and shipment.	This language is proposed based on the need to adopt standards to assure that the integrity of medication obtained via an Internet or mail order pharmacy is maintained during storage and shipment.

**ATTACHMENT A**

**TASK FORCE ON INTERNET  
PHARMACIES AND PRESCRIBING**

MEETING DATES

January 31, 2000

March 6, 2000

April 16, 2000

May 22, 2000

June 26, 2000

September 20, 2000  
(Public Hearing)

January 8, 2001

## ATTACHMENT C

### DEFINITIONS

*The following definitions from the Michigan Public Health Code are relevant to the discussion of Internet pharmacy practice.*

333.17707 (5) "Practice of pharmacy" means a health service, the clinical application of which includes the encouragement of safety and efficacy in prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

- (a) The interpretation and evaluation of a prescription.
- (b) Drug product selection
- (c) The compounding, dispensing, safe storage, and distribution of drugs and devices.
- (d) The maintenance of legally required records.
- (e) Advising the prescriber and the patient as required as to contents, therapeutic action, utilization, and possible adverse reactions or interactions of drugs.

333.17708(2) "Prescriber" means a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under part 174 to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

## ATTACHMENT D

### VERIFIED INTERNET PHARMACY PRACTICE SITE (VIPPS) CRITERIA

#### Licensure

Qualifying VIPPS Pharmacies will:

1. Provide NABP with the information necessary to verify that the VIPPS pharmacy is licensed or registered in good standing to operate a pharmacy and/or engage in the practice of pharmacy with all applicable jurisdictions;
2. Provide NABP with the information necessary to verify that all persons affiliated with the site, including those affiliated through contractual or other responsible arrangements, that are engaging in the practice of pharmacy are appropriately licensed or registered and in good standing in all applicable jurisdictions; and
3. Agree to comply with all applicable statutes and regulations governing the practice of pharmacy where licensed or registered. When a conflict arises between individual state laws or regulations, or between state and federal laws or regulations, the VIPPS Pharmacy will agree to comply with the more stringent law or regulation that applies as determined by conflict-of-law rules.

#### Prescriptions

VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations will:

4. Maintain and enforce policies and procedures that assure the integrity, legitimacy, and authenticity of the Prescription Drug Order and seek to prevent Prescription Drug Orders from being submitted, honored, and filled by multiple pharmacies; and
5. Maintain and enforce policies and procedures that assure compliance with applicable generic substitution statutes and regulations and prohibit unauthorized therapeutic substitution from occurring without the necessary patient or prescriber authorization and outside of the conditions for participation in state or federal programs, such as Medicaid.

#### Patient Information

VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations, will:

6. Maintain and enforce policies and procedures ensuring reasonable verification of

the identity of the patient, prescriber, and if appropriate, caregiver, in accordance with applicable state law.

7. Obtain and maintain in a readily accessible format, patient medication profiles and other related data in a manner that facilitates consultation with the prescriber, when applicable, and counseling of the patient or caregiver;
8. Conduct a prospective drug use review (DUR) prior to the dispensing of a medication or device in accordance with applicable state law; and
9. Maintain and enforce policies and procedures to assure patient confidentiality and protect patient identity and patient-specific information from inappropriate or non-essential access, use, or distribution. [The NABP Guidelines for the Confidentiality of Patient Health Care Information as IT Relates to Patient Compliance and Patient Intervention Programs can serve as a useful resource for addressing the confidentiality and security of patient data.]

#### **Communication**

VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria will:

10. Maintain and enforce policies and procedures requiring pharmacists to offer interactive, meaningful consultation to the patient or caregiver;
11. Maintain and enforce policies and procedures establishing a mechanism for patients to report and the VIPPS Pharmacy to take appropriate action regarding suspected adverse drug reactions and errors;
12. Maintain and enforce policies and procedures that provide a mechanism to contact the patient and, if necessary, the prescriber if an undue delay is encountered in delivering the prescribed drug or device. Undue delay is defined as an extension of the normal delivery cycle sufficient to jeopardize or alter the patient treatment plan; and
13. Maintain and enforce policies and procedures establishing mechanisms to inform patients or caregivers about drug recalls and to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications.

#### **Storage and Shipment**

VIPPS Pharmacies, in accordance with applicable state and federal laws and regulations and VIPPS program criteria, will:

14. Ship controlled substances to patients via a secure and traceable means; and
15. Assure that medications and devices are maintained within appropriate temperature, light, and humidity standards as established by the United States Pharmacopoeia (USP) during storage and shipment.

#### **Over-the-Counter Products**

VIPPS Pharmacies will:

16. Comply with all applicable federal and state laws regarding the sale of Over-the-Counter Products identified as precursors to the manufacture or compounding of illegal drugs.

#### **Quality Improvement Program**

VIPPS Pharmacies will:

17. Maintain a Quality Assurance/Quality Improvement Program.

#### **Reporting to NABP**

VIPPS Pharmacies will:

18. Notify NABP within 30 days of any change of information provided as part of the verification process or involving data displayed on the VIPPS website;
19. Notify NABP of any change of the Pharmacist-in-Charge; and
20. Provide and maintain a link from the VIPPS Seal on the pharmacy's website to the VIPPS website in a form and manner acceptable to NABP.

#### **Reporting by NABP**

VIPPS Pharmacies will receive from NABP:

21. A listing on the VIPPS website, provided the listing is not deemed an endorsement of the listed pharmacy by NABP for the quality of care provided and is not utilized by the VIPPS Pharmacy in advertisements inferring such an endorsement; and
22. A licensing agreement permitting the VIPPS site to display the VIPPS seal on its website provided the advertisement or promotion does not imply an endorsement by NABP of the VIPPS Pharmacy, its services, or its products.

## **ATTACHMENT K**

*Proposed Board of Pharmacy General Rules  
(Incorporated into the Pharmacy General rules in FY 2007)*



DEPARTMENT OF COMMUNITY HEALTH

DIRECTOR'S OFFICE

PHARMACY - GENERAL RULES

(By authority conferred on the director of the department of community health by sections 16145(3) and 17701 of 1978 PA 368, MCL 333.16145(3) and 333.17701 et seq. and Executive Reorganization Order Nos. 1996-1, 1996-2, and 2003-01, being MCL 330.3101, 445.2001, and 445.2011)

PART 1. GENERAL PROVISIONS

R 338.471 Repealer.

Rule 1. All rules and regulations previously adopted by the state board of pharmacy, hereinafter referred to as the board, are hereby repealed and set aside.

History: 1979 AC.

R 338.471a Definitions.

Rule 1a. As used in these rules:

(a) "Accredited college or school of pharmacy" means a college or school of pharmacy that is accredited by the accreditation council for pharmacy education, as provided in R 338.474(1) (a).

(b) "Board" means the board of pharmacy.

(c) "Code" means 1978 PA 368, MCL 333.1101.

(d) "Department" means the department of community health.

(e) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

An electronic signature also is a unique identifier protected by appropriate security measures such that it is only available for use by the intended individual and ensures non-repudiation so that the signature may not be rejected based on its validity.

(f) "Unconventional internship" means an educational program of professional and practical experience involving those pharmacy or related pharmaceutical experiences which, by practical, on-the-job training, provide knowledge useful to the practice of the profession of pharmacy without meeting all of the criteria of a conventional internship.

History: 1980 AACs; 1986 AACs; 2007 AACs.

R 338.472 Prescription drugs and devices; return or exchange for resale prohibited.

Rule 2. (1) For the protection of the public health and safety, prescription drugs or devices which have been dispensed and which have left the control of the pharmacist shall not be returned or exchanged for resale.

(2) Subrule (1) of this rule does not apply to a pharmacy operated by the department of corrections or under contract with the department

of corrections or a county jail that has accepted a prescription drug for resale or redispensing, as provided under section 17766d of the code.

History: 1979 AC; 1980 AACS; 2007 AACS.

R 338.473 Intern licensure; eligibility; renewal; limitations.

Rule 3. (1) An applicant for a pharmacy intern license shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall establish that he or she is admitted to and actively enrolled in a professional program of study within an accredited college or school of pharmacy, as provided in R 338.474(1) (a).

(2) An intern shall engage in the practice of pharmacy only under the supervision of a pharmacist preceptor as defined in section 17708(1) of the code and only under the personal charge of a pharmacist.

History: 1979 AC; 1980 AACS; 1990 AACS; 2007 AACS.

R 338.473a Interns; eligibility; limited license; qualifications; supervision; notice of position change; duties; professional and practical experience; denial, suspension, or revocation of license.

Rule 3a. (1) An individual is eligible for intern licensure at the beginning of the first professional year of study in an accredited college or school of pharmacy.

(2) Upon application and payment of appropriate fees, a limited license shall be issued by the department to qualified applicants. The limited license shall remain active while the applicant is actively pursuing a degree in an accredited college or school of pharmacy and until licensure as a pharmacist or for not more than 1 year from the date of graduation from such college or school of pharmacy, unless extended by the board upon written request of the intern.

(3) An intern shall complete not less than 1,000 hours of internship experience, 500 hours of which shall be completed during the 18 months immediately preceding the examination for pharmacist licensure.

An intern working in Michigan shall hold an intern license in order to earn the hours of internship experience required in Michigan. The minimum number of hours of internship experience may be satisfied by complying with any of the following provisions:

(a) Obtaining the minimum number of hours of experience under the personal charge of a qualified, approved preceptor.

(b) Completing a board-approved, structured practical experience program within the college or school of pharmacy curriculum.

(c) Through a combination of subdivisions (a) and (b) of this subrule.

(4) When eligible, a student shall apply for licensure as an intern.

(5) Hours of internship experience shall be computed from the date of board certification as a licensed intern. In computing the hours of internship experience, all of the following provisions shall apply:

(a) Experience shall be granted only upon verification by an approved pharmacy preceptor or other person previously approved by the board.

(b) The board may grant internship experience gained in unconventional internship programs. Up to 400 hours of internship experience may be granted for such unconventional education experiences.

(c) A maximum of 40 hours of internship experience shall be granted per calendar week served by the intern.

(d) A maximum of 16 hours of non-college-sponsored internship experience shall be granted per calendar week while the intern is a full-time student in a college or school of pharmacy, except during authorized vacation periods.

(e) The board may grant credit for internship experience obtained through practice as an intern in another jurisdiction if the experience was comparable to the minimum standards set forth in these rules.

(f) The board may accept experience as a licensed pharmacist in another jurisdiction as the equivalent of internship experience.

(6) An intern shall be supervised by an approved pharmacist preceptor and shall, at all times, practice only under the personal charge of a pharmacist.

The intern shall be responsible for verifying board approval of his or her pharmacy preceptor.

(7) Within 30 days, an intern also shall notify the board if he or she is no longer actively enrolled in a pharmacy degree program at an accredited college or school of pharmacy.

(8) Interns shall complete and submit such forms or examinations, or both, as deemed necessary by the board.

(9) Interns shall receive professional and practical experience in at least all of the following areas:

(a) Pharmacy administration and management.

(b) Drug distribution, use, and control.

(c) Legal requirements.

(d) Providing health information services and advising patients.

(e) Pharmacists' ethical and professional responsibilities.

(f) Drug and product information.

(10) Interns shall keep abreast of current developments in the internship program and the pharmacy profession.

(11) The board may deny, suspend, or revoke the license of an intern or may deny hours of internship for failure to comply with pharmacy law or rules relating to pharmacy practice or internship.

History: 1979 AC; 1980 AACS; 1986 AACS; 2007 AACS.

R 338.473b Rescinded.

History: 1979 AC; 1980 AACS; 1986 AACS.

R 338.473c Preceptors; approval; qualifications; duties; denial, suspension, or revocation of preceptor approval.

Rule 3c. (1) Before training an intern, a licensed pharmacist in this state shall apply to the board for approval as a preceptor. A pharmacist shall have at least 1 year of practice before being approved as a preceptor.

(2) There shall be not more than 2 interns per pharmacist on duty at the same time. However, the approved preceptor is responsible for the overall internship program at the pharmacy.

(3) A preceptor is responsible for arranging the intern's training in areas of practice as defined in R 338.473a(9).

(4) A preceptor shall annually submit internship training affidavits on forms provided by the board.

(5) The preceptor shall determine the degree of professional skill possessed by the intern and shall develop a training program whereby the intern will be able to improve upon and develop his or her ability in the practice of pharmacy.

(6) The preceptor shall allow sufficient time to instruct the intern in the practice of pharmacy and to frequently review and discuss his or her progress.

(7) Upon completion of the intern training, the preceptor under whom the training was obtained shall give the preceptor's opinion on the ability of the intern to practice pharmacy without supervision. If the preceptor's report is not satisfactory, the board may require further training before allowing the intern to take the examination for licensure as required by R 338.474.

(8) The board may deny, suspend, or revoke the preceptor's approval for failure to properly supervise the intern during the internship training program or for violation of the laws and rules relating to the practice of pharmacy or the internship program.

(9) The board may deny, suspend, or revoke the preceptor's approval of a pharmacist who has been convicted of any violation of a federal, state, or local law, ordinance, or rules relating to pharmacy practice within 5 years of the application for approval as a preceptor.

History: 1980 AACS; 1986 AACS.

R 338.473d Graduates of a non-accredited college or school of pharmacy; requirements; internship.

Rule 3d. (1) An applicant who is a graduate of a non-accredited college or school of pharmacy may be granted an intern license to comply with the requirements of R 338.473a(3) upon making application, payment of appropriate fees, and providing evidence of successful completion of the Foreign Pharmacy Graduate Examination Committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056.

(2) An intern license issued in accordance with this rule is valid for not more than 2 years from the date of issuance, unless extended by the board upon written request by the intern.

History: 1986 AACS; 2007 AACS.

R 338.474 Pharmacist licensure; eligibility; examination.

Rule 4. (1) An applicant for licensure as a pharmacist shall submit a completed application on a form provided by the department, together with the appropriate fee. In addition to meeting the requirements of the code and the administrative rules promulgated pursuant thereto, an applicant shall comply with all of the following requirements:

(a) Have completed the requirements for a degree in pharmacy from an accredited college or school of pharmacy education approved by the board or successfully completed the Foreign Pharmacy Graduate Examination Committee certification program administered by the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Dr., Mount Prospect, IL 60056. The board adopts by reference the standards of the

Accreditation Council for Pharmacy Education, 20 North Clark St., Suite 2500, Chicago, IL 60602. The standards are set forth in the documents entitled "Standards and Guidelines for Accreditation of Professional Degree Programs in Pharmacy", 8th edition, January 1995; and, the "Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree", adopted June 14, 1997, of the Accreditation Council for Pharmacy Education. copies of the standards are available at no cost from the Council's website at <http://www.acpe-accredit.org/standards>.

Copies of the guidelines also are available for inspection and distribution at cost from the Michigan Board of Pharmacy, Department of Community Health, 611 West Ottawa, P.O. Box 30670, Lansing, MI 48909.

(b) Have completed a program of internship pursuant to these rules.

(c) Pass a jurisprudence examination, approved by the board, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy with a scaled score of not less than 75.

(d) Pass an examination, approved by the board, which measures an applicant's theoretical and practical knowledge of pharmacy with a scaled score of not less than 75.

(2) An applicant who has not achieved a passing score on either of the examinations identified in subrule (1)(c) and (d) of this rule after 6 attempts may be reexamined only after meeting the requirements set forth in R 338.474a.

History: 1979 AC; 1980 AACS; 1988 AACS; 2007 AACS.

R 338.474a Licensure; reexamination.

Rule 4a. An applicant may take the examinations required by these rules on 6 separate occasions. An applicant who has not received a passing score on an examination after 6 attempts shall not take the examination a seventh or subsequent time, unless the applicant can demonstrate to the board that the applicant has complied with all of the following:

(a) Has enrolled as a student in a pharmacy education program approved by the board.

(b) Has taken courses which would provide a thorough review of those areas failed on the applicant's most recent examination.

(c) Has submitted certification to the board from the pharmacy education institution that the courses have been satisfactorily completed.

History: 1983 AACS; 2007 AACS.

R 338.475 Licensure by endorsement; examination.

Rule 5. An applicant for licensure by endorsement shall submit a completed application on a form provided by the department, together with the requisite fee. In addition to meeting the requirements of the code and administrative rules promulgated pursuant thereto, an applicant shall satisfy both of the following requirements:

(a) Pass an examination, approved by the board, which measures an applicant's knowledge of the rules and regulations governing the practice of pharmacy with a scaled score of not less than 75.

(b) Satisfy those requirements in existence in this state at the time he or she was licensed in another state.

History: 1979 AC; 1980 AACS; 1990 AACS; 2007 AACS.

R 338.476 Rescinded.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.477 Pharmacy licenses; applications; notice of changes; self-inspection reports.

Rule 7. (1) Each separate pharmacy location where drugs are prepared or dispensed shall be licensed by the board under section 17741 of the code.

If multiple locations under the same ownership exist at a single street address and share a central inventory, then only 1 license is required.

(2) A licensee who is moving to a new location shall apply and be approved for a new license for each location before moving. The department shall provide license applications. A licensee shall pay a license fee to the department for each new location.

(3) An applicant that is a partnership or corporation or that operates under an assumed name shall file, with its application for a pharmacy license, certified copies of its partnership certificates, corporate articles, or assumed name certificate. This requirement shall be waived if the application is for additional units and the additional units will be under the same ownership.

(4) A partnership, corporation, or entity operating under an assumed name shall provide the board with written notification of a change in any of the following entities:

- (a) Partners.
- (b) Stockholders.
- (c) Officers.
- (d) Members of the board of directors.

(e) The individual pharmacist who is designated as the pharmacy licensee of a licensed pharmacy.

A partnership or corporation shall notify the board within 30 days of the change.

A publicly held corporate pharmacy need not report changes in stockholders.

(5) A person who applies for new pharmacy license or pharmacy relocation shall send an application and a completed self-inspection report on forms provided by the department.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.477a Application for license by governmental entity.

Rule 7a. An application by a governmental entity for a new or renewal pharmacy, drug manufacturer's, or wholesaler's license shall designate an individual to be the licensee. That individual and the pharmacist on duty are responsible for compliance with federal and state laws regulating the distribution of drugs and the practice of pharmacy.

History: 1979 AC.

R 338.477b Requirements for relicensure.

Rule 7b. (1) An applicant for relicensure who has had a lapsed license for 3 years or less under the provisions of section 16201(3) of the code may be relicensed upon compliance with both of the following requirements:

(a) Submission of a completed application on a form provided by the department, together with the requisite fee.

(b) Submission of proof of completion of 30 hours of continuing education that has been earned within the 2-year period immediately preceding the application for relicensure.

(2) An applicant for relicensure who has had a lapsed license for more than 3 years under the provisions of sections 16201(4) and 17733 of the code shall, in addition to the requirements set forth in subrule (1) of this rule, take and pass the board's jurisprudence examination with a score of not less than 75 and have been licensed and engaged in the practice of pharmacy in another state during the period that the applicant's Michigan license is expired or complete a program of practical pharmacy experience that is not less than 200 hours as follows:

(a) The individual shall practice under the personal charge of a currently licensed pharmacist.

(b) The individual shall notify the board, in writing, of the name of the supervising pharmacist and the name and address of the pharmacy before beginning the required practical experience.

(c) When an applicant has completed the required practical experience, the supervising pharmacist shall provide the board with verification of the applicant's completion of the experience.

(3) For purposes of subrule (2) of this rule, "completion of a program of practical pharmacy experience" means professional and clinical instruction in at least all of the following areas:

(a) Pharmacy administration and management.

(b) Drug distribution, use, and control.

(c) Legal requirements.

(d) Providing health information services and advising patients.

(e) Pharmacist's ethical and professional responsibilities.

(f) Drug and product information.

(4) For purposes of complying with the provisions of subrule (2) of this rule, an applicant may be granted a temporary, nonrenewable license to complete the practical experience.

History: 1980 AACS; 1986 AACS; 1998-2000 AACS.

R 338.478 "Person" defined.

Rule 8. The word "person," as used in all statutes, rules, and regulations relating to the profession of pharmacy, shall be construed to include individuals, partnerships, firms, corporations, associations and governmental institutions.

History: 1979 AC.

R 338.479 Prescription drug labeling.

Rule 9. (1) All labeling of prescription drugs shall comply with the requirements of the code and the federal food, drug, and cosmetic act, 21 U.S.C. S301 et seq.

(2) All containers in which prescription medication is dispensed shall bear a label which contains, at a minimum, all of the following information:

- (a) Pharmacy name and address.
- (b) Prescription number.
- (c) Patient's name.
- (d) Date the prescription was most recently dispensed.
- (e) Prescriber's name.
- (f) Directions for use.
- (g) The name of the medication, unless the prescriber indicates "do not label."

(3) If a drug is dispensed that is not the brand prescribed, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed. If the dispensed drug does not have a brand name, the prescription label shall indicate the name of the brand prescribed followed by the generic name of the drug dispensed or the reference "G.Eq.," "generic," or "generic equivalent" in the case of multi-ingredient products. This subrule does not apply if the prescriber indicates "do not label."

(4) If drug product selection takes place, the brand name or the name of the manufacturer or supplier of the drug dispensed shall be noted on the prescription.

(5) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACS.

R 338.479a Prescription drug receipts.

Rule 9a. (1) The purchaser of a prescription drug shall receive, at the time the drug is delivered to the purchaser, a receipt which contains all of the following information:

- (a) The brand name of the drug dispensed, if applicable, unless the prescriber indicates "do not label."
- (b) The name of the manufacturer or supplier of the drug if the drug has no brand name, unless the prescriber indicates "do not label."
- (c) The strength of the drug, if significant, unless the prescribed indicates "do not label."
- (d) The quantity dispensed, if applicable.
- (e) The name and address of the pharmacy.
- (f) The serial number of the prescription.
- (g) The date the prescription was most recently dispensed.
- (h) The name of the prescriber.
- (i) The name of the patient for whom the drug was prescribed.
- (j) The price for which the drug was sold to the purchaser.

(2) Notwithstanding R 338.479, the information mandated in this rule shall appear on either the prescription label or on a combination label and receipt.

(3) For prescription services that are covered by a third party pay contract, the price included in the receipt is the amount actually paid by the patient.

(4) A pharmacist shall retain a copy of the receipt for a period of 90 days. The inclusion of the information required in this rule on the written prescription form and the retention of the form constitutes retaining a copy of the receipt. The physical presence of the prescription form in the pharmacy constitutes compliance with the



requirement of having the name and address of the pharmacy on the form.

(5) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACs.

R 338.479b Noncontrolled prescriptions.

Rule 9b. (1) A prescriber who issues a prescription for a noncontrolled legend drug shall date and sign the prescription and shall ensure that the prescription contains all of the following information:

(a) The full name of the patient for whom the drug is being prescribed.

(b) The prescriber's printed name and address.

(c) The drug name and strength.

(d) The quantity prescribed.

(e) The directions for use.

(f) The number of refills authorized.

(2) A prescriber shall ensure that a prescription is legible and that the information specified in subrule (1)(c) to (f) of this rule is clearly separated.

(3) A prescriber shall not prescribe more than the following on a single prescription form as applicable:

(a) For a prescription prescribed in handwritten form, up to 4 prescription drug orders.

(b) For a prescription prescribed on a computer-generated form or a preprinted list or produced on a personal computer or typewriter, up to 6 prescription drug orders.

(4) A prescriber shall not add handwritten drugs to a preprinted form and shall clearly designate which drugs are to be dispensed.

(5) A prescriber shall not prescribe a controlled and noncontrolled substance on the same prescription form.

(6) A prescription is valid for 1 year from the date the prescription was issued.

(7) A prescriber shall clearly indicate the total number of drugs prescribed for each prescription.

(8) A noncontrolled substance prescription may be transmitted electronically from the prescriber to the pharmacy of the patient's choice, and shall occur by utilizing a system that includes the following:

(a) A combination of technical security measures such as, but not limited to, those listed in R 164.312 under Subpart C - Security Standards for the Protection of Electronic Protected Health Information of 45 CFR Part 164 that implements the federal Health Insurance Portability and Accountability Act of 1996, to ensure all of the following:

(i) Authentication of an individual who prescribes or dispenses.

(ii) Technical non-repudiation.

(iii) Content integrity.

(iv) Confidentiality.

(b) An electronic signature as defined in R 338.471a(e). An electronic signature is valid only when it is used to sign a prescription that is transmitted electronically from a prescriber to a pharmacy.

(c) Appropriate security measures to invalidate a prescription if either the electronic signature or prescription record to which it is attached or logically associated is altered or compromised following transmission by the prescriber. The electronic prescription may be reformatted to comply with industry standards provided that no data is added, deleted, or changed.

(9) The electronic prescription shall meet any other requirements of the federal Health Insurance Portability and Accountability Act.

(10) The electronic prescription shall permit the prescriber to instruct the pharmacist to dispense a brand name drug product provided that the prescription includes both of the following:

(i) The indication that no substitute is allowed, such as "dispense as written" or "DAW".

(ii) The indication that no substitute is allowed and that it is a unique element in the prescription.

(11) If the prescription is transmitted electronically, the prescriber shall generate and transmit the prescription in a format that can be read and stored by a pharmacy in a retrievable and readable form. The electronic prescription shall identify the name of the pharmacy intended to receive the transmission, and shall include the information identified in subrule (1) of this rule.

(12) The electronic prescription shall be preserved by a licensee or dispensing prescriber for not less than 5 years. A paper version of the electronic prescription shall be made available to an authorized agent of the board upon request. A secured copy shall be retained for a minimum of 1 year by the transaction service vendor for record-keeping purposes and shall be shared only with the parties involved in the transaction except as otherwise permitted by state or federal law.

(13) An electronic signature that meets the requirements of this rule shall have the full force and effect of a handwritten signature on a paper-based written prescription.

(14) This rule does not apply to inpatient medical institutions.

History: 1998-2000 AACS; 2000 AACS; 2007 AACS.

R 338.479c Customized patient medication packages (CPMP).

Rule 9c. (1) In place of dispensing 2 or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (CPMP). A CPMP is a package which is prepared by a pharmacist for a specific patient and which contains 2 or more prescribed solid oral dosage forms. The CPMP is designed and labeled to indicate the day and time or period of time that the contents within each CPMP are to be taken.

The person who dispenses the medication shall instruct the patient or caregiver on the use of the CPMP.

(2) If medication is dispensed in a CPMP, then all of the following conditions shall be met:

(a) Each CPMP shall bear a clearly readable label that states all of the following information:

(i) A serial number for the CPMP itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained in the CPMP.

(ii) The name, strength, physical description, and total quantity of each drug product contained in the CPMP.

(iii) The name of the prescriber for each drug product.

(iv) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product in the CPMP.

(v) The date of the preparation of the CPMP.

(vi) An expiration date for the CPMP. The date shall not be later than the earliest manufacturer's expiration date for any medication included in the CPMP or 60 days after the date of dispensing.

(vii) The name, address, and telephone number of the dispenser.

(viii) Any other information, statements, or warnings required for any of the drug products contained in the CPMP.

(b) A CPMP shall be accompanied by a patient package insert in case any medication in the CPMP is required to be dispensed with an insert as accompanying labeling. Alternatively, required medication information may be incorporated by the pharmacist into a single educational insert that includes information regarding all of the medications in the CPMP.

(c) In the absence of more stringent packaging requirements for any of the drug products contained in the CPMP, each CPMP shall be in compliance with the United States pharmacopeia (USP) and national formulary, as defined in section 17706(2) of the code, for moisture permeation requirements for a class b single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened. All provisions of the poison prevention packaging act, as defined in section 17761(2) of the code, shall be complied with.

(d) When preparing a CPMP, the dispenser shall take into account any applicable compendial requirements or guidelines, the physical and chemical compatibility of the dosage forms placed within each container, and any therapeutic incompatibilities that may attend the simultaneous administration of the medications.

Medications shall not be dispensed in CPMP packaging in any of the following situations:

(i) The USP monograph or official labeling requires dispensing in the original container.

(ii) The drugs or dosage forms are incompatible with packaging components or each other.

(iii) The drugs are therapeutically incompatible when administered simultaneously.

(iv) The drug products require special packaging.

(e) If 2 medications have physical characteristics that make them indistinguishable from each other, then the medication shall not be packaged together in the same CPMP.

(f) Medications that have been dispensed in CPMP packaging may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason.

If a prescription for any drug contained in the CPMP is changed, then a new appropriately labeled CPMP shall be prepared for the patient.

(g) In addition to all individual prescription filing requirements, a record of each CPMP dispensed shall be made and filed. At a minimum each record, shall contain all of the following information:

(i) The name and address of the patient.

(ii) The serial number of the prescription order for each drug product contained in the CPMP.

(iii) Information identifying or describing the design, characteristics, or specifications of the CPMP sufficient to allow subsequent preparation of an identical CPMP for the patient.

(iv) The date of preparation of the CPMP and the expiration date assigned.

- (v) Any special labeling instructions.
- (vi) The name or initials of the pharmacist who prepared the CPMP.

History: 1998-2000 AACS.

R 338.480 Prescription records; nonapplicability to inpatient medical institution service.

Rule 10. (1) A prescription shall be numbered, dated, and initialed by the dispensing pharmacist at the time of the first filling at the pharmacy.

(2) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.

(3) This rule does not apply to inpatient medical institution service.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.480a Prescription refill records; manual systems; profile systems; automated data processing systems; nonapplicability to inpatient medical institution service; record confidentiality and access.

Rule 10a. (1) A pharmacist shall record prescription refills using only 1 of the systems described in subrule (2), (3), or (4) of this rule and in compliance with the provisions of subrule (2), (3), or (4) of this rule, as applicable.

(2) A pharmacy may utilize a manual system of recording refills if the system is in compliance with both of the following criteria:

(a) The amount and date dispensed shall be entered on the prescription in an orderly fashion and the dispensing pharmacist shall initial the entry.

If the pharmacist only initials and dates the prescription, then the full face amount of the prescription shall be deemed dispensed.

(b) If the drug that is dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated on the prescription.

(3) A pharmacy may utilize a uniform system of recording refills if the system is in compliance with all of the following criteria:

(a) Records shall be created and maintained in written form. All original and refill prescription information for a particular prescription shall appear on single documents in an organized format. The pharmacy shall preserve the records for 5 years. The records are subject to inspection by the board or its agents.

(b) All of the following information for each prescription shall be entered on the record:

- (i) The prescription number.
- (ii) The patient's name and address.
- (iii) The prescriber's name.
- (iv) The prescriber's federal drug enforcement administration number, if appropriate.
- (v) The number of refills authorized.
- (vi) The "dispense as written" instructions, if indicated.

(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(c) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries and shall initial the record each time a prescription is filled or refilled.

(d) The information required by subdivision (b) of this subrule shall be entered on the record for all prescriptions filled at a pharmacy, including nonrefillable prescriptions. This requirement is in addition to the requirements set forth in R 338.480.

(4) A pharmacy may utilize a uniform automated data processing system of recording refills if the system is in compliance with all of the following criteria:

(a) All information that is pertinent to a prescription shall be entered on the record, including all of the following information:

(i) The prescription number.

(ii) The patient's name and address.

(iii) The prescriber's name.

(iv) The prescriber's federal drug enforcement administration number, if appropriate.

(v) The number of refills authorized.

(vi) Whether the drug must be dispensed as written.

(vii) The name, strength, dosage form, and quantity of the drug prescribed and the drug dispensed originally and upon each refill. If the drug dispensed is other than the brand prescribed or if the prescription is written generically, then the name of the manufacturer or supplier of the drug dispensed shall be indicated.

(viii) The date of issuance of the prescription.

(ix) The date and identifying designation of the dispensing pharmacist for the original filling and for each refill.

(b) Prescription entries shall be made on the record at the time the prescription is first filled and at the time of each refill, except that the format of the record may be organized so that information already entered on the record may appear for a prescription or refill without reentering the information. The dispensing pharmacist is responsible for the completeness and accuracy of the entries. The pharmacy shall preserve the records on-site for 5 years. The records are subject to inspection by the board or its agents.

A procedure shall be established to facilitate inspections.

(c) The required information shall be entered on the record for all prescriptions filled at the pharmacy, including nonrefillable prescriptions.

This requirement is in addition to the requirements set forth in R 338.480.

(d) The recording system shall provide adequate safeguards against

improper manipulation, the alteration of records, and the loss of records.

(e) The recording system shall have the capability of producing a printout of all original and refilled prescription data, including a prescription-by-prescription and refill-by-refill audit trail for any specified strength and dosage form of a controlled substance by either brand or generic name or an audit trail of controlled substance prescriptions written for a particular patient or by a particular practitioner. A printout of an audit trail or other required information shall be made available to an authorized agent of the board upon request. The prescription data shall be maintained for 5 years. Data older than 16 months shall be provided within 72 hours of the time the request is first made by the agent. Prescription data for the most current 16 months shall be readily retrievable on site and available for immediate review.

(f) If the automated data processing system is inoperative for any reason, then the pharmacist shall ensure that all refills are authorized and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the pharmacist shall enter the information regarding prescriptions filled and refilled during the inoperative period into the automated data processing system within 48 hours.

(g) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with the supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records.

(h) The automated data processing system shall be an integrated system that is capable of complying with all of the requirements of these rules.

(5) This rule does not apply to inpatient medical institution service.

(6) Records that are created under subrule (3) or (4) of this rule are subject to the same requirements regarding confidentiality and access that apply to original prescriptions.

History: 1992 AACS; 1998-2000 AACS.

R 338.481 Professional and technical equipment and supplies.

Rule 11. (1) A pharmacy shall be equipped with necessary drawers, shelves, storage cabinets, and prescription files. A sink that has hot and cold running water and a refrigerator of reasonable capacity shall be in the pharmacy department.

(2) A pharmacy shall have current editions or revisions of the Michigan pharmacy laws and rules and not less than 2 current or revised pharmacy reference texts that pertain to pharmacology, drug interactions, or drug composition. A current electronic medium version of pharmacy reference texts meets the requirements of this subrule.

(3) A pharmacy shall have the necessary technical equipment to compound and dispense prescription drugs.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.482 Housing of pharmacy.

Rule 12. (1) All professional and technical equipment and supplies and prescription drugs shall be housed in a suitable, well-lighted

and well-ventilated room or department with clean and sanitary surroundings.

(2) All pharmacies shall have a prescription department which is devoted primarily to the compounding of prescriptions and the manufacture of pharmaceutical preparations which occupies not less than 150 square feet of space, and which includes a prescription counter that provides not less than 10 square feet of free working surface. If more than 1 pharmacist is on duty at any one time, the free working space shall be increased by not less than 4 square feet for each additional pharmacist. The prescription counter shall be kept clean and orderly. The space behind the prescription counter shall be sufficient to allow free movement within the area and shall be free of obstructions.

(3) All pharmacies that occupy less than the entire area of the premises owned, leased, used, or controlled by the licensee shall be permanently enclosed by partitions from the floor to the ceiling. All partitions shall be of substantial construction and shall be securely lockable so that drugs and devices that can only be sold by a pharmacist are unobtainable during the absence of the pharmacist. Identification of this department by the use of the words "drug," "medicines," or "pharmacy" or by the use of a similar term or combination of terms shall be restricted to the area that is registered by the board. The pharmacy department shall be locked when the pharmacist is not in the establishment.

History: 1979 AC; 1980 AACS.

R 338.483 Rescinded.

History: 1979 AC; 1992 AACS.

R 338.484 Rescinded.

History: 1954 ACS 37, Eff. Feb. 14, 1964; rescinded 1954 ACS 77, Eff. Sept. 26, 1973.

#### ADMINISTRATIVE HEARINGS

R 338.485 - R 338.485y Rescinded.

History: 1979 AC; 1980 AACS.

R 338.486 "Medical institution" and "pharmacy services" defined; pharmacy services in medical institutions.

Rule 16. (1) As used in this rule:

(a) "Medical institution" means a hospital, skilled nursing facility, county medical care facility, nursing home, or other health facility which is licensed or approved by the state and which directly or indirectly provides or includes pharmacy services.

(b) "Pharmacy services" means the direct and indirect patient care services associated with the practice of pharmacy.

(2) Pharmacy services shall be directed and provided by a licensed

pharmacist.

(3) Pharmacy personnel who assist the pharmacist by performing delegated functions in the care of inpatients shall be supervised by a pharmacist who is on the premises of the medical institution.

(4) The pharmacist who directs the pharmacy services shall develop, implement, supervise, and coordinate all of the services provided, including, at a minimum, all of the following:

(a) Dispensing medications in a form that minimizes additional preparation before administration to the patient, including the admixture of parenterals.

(b) Obtaining the prescriber's original medication order, a direct carbonized copy, an electromechanical facsimile, or other electronic order transmission. Security measures shall be in place to ensure that system access by unauthorized individuals is not allowed.

(c) Interpreting and reviewing the prescriber's medication orders and communicating problems with these orders to the physician or nurse before administration of first doses. If the interpretation and review will cause a medically unacceptable delay, then a limited number of medications may be stocked at the patient care areas for the administration of first doses.

These medications shall be provided in a manner that ensures security and immediate availability, such as sealed or secured medication kits, carts, or treatment trays.

A pharmacist shall routinely inspect the medications and, after use, shall verify the contents and replace the medications as necessary.

(d) Monitoring medication therapy to promote positive patient outcomes while evaluating clinically significant chemical and therapeutic incompatibilities.

(e) Establishing the specifications for the procurement of all pharmaceuticals and related biologicals and chemicals approved for use in the medical institution.

(f) Periodically inspecting all areas in the medical institution where medications are stored to verify compliance with the standards for the safe use and storage of the medications.

(g) Maintaining proper security for all medications stored or kept within the medical institution.

(h) Providing educational programs regarding medications and their safe use.

(i) Providing a method by which medications can be obtained during the absence of a pharmacist in a medical institution where a pharmacist is not available 24 hours a day. The method shall minimize the potential for medication error. During the absence of a pharmacist, the services of a pharmacist shall be available on an on-call basis. Only a limited number of medications that are packaged in units of use shall be available.

The medications shall be approved and reviewed periodically as deemed necessary, but not less than once a year, by an appropriate interdisciplinary practitioner committee of the medical institution. The medication shall be kept in a securely locked, substantially constructed cabinet or its equivalent in an area of limited access in a centralized area outside the pharmacy. Each medication shall be labeled to include the name of the medication, the strength, the expiration date, if dated, and the lot number.

A written order and a proof of removal and use document shall be obtained for each medication unit removed. The order and document shall be reviewed by the pharmacist within 48 hours of removing medication from the cabinet or its equivalent. The pharmacist who



directs pharmacy services in the medical institution shall designate the practitioners who are permitted to remove the medication. A pharmacist shall audit the storage locations as often as needed to guarantee control, but not less than once every 30 days.

(5) Upon recommendation of an interdisciplinary practitioners committee, the pharmacist who directs pharmacy services in the medical institution shall adopt written policies and procedures to promote safe medication practices, to conduct medication utilization review, to approve medications for the medical institution's formulary or medication list, and to promote positive patient outcomes. A pharmacist shall meet with the committee at least quarterly to conduct assigned responsibilities.

(6) A pharmacy shall ensure that every medication dispensed is identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. A pharmacy that is engaged in drug distribution to medical institutions which use unit-of-use packaging shall place identification on the label of its package to allow the package to be readily traced. The name of the patient and any identifying number shall be labeled on the medication container. The container may be the individual patients' assigned medication drawer. The directions for use shall be on the label of the container if the directions are not communicated in another effective manner. If the medication is to be self-administered, then directions for use shall be on the container. The preceding provisions of this subrule are minimum labeling standards only and do not supersede other applicable laws or rules.

(7) A pharmacist shall personally supervise the destruction of unused portions of prescription medication, other than controlled substances under part 71 of the code, dispensed to patients. However, medications in single-unit packages and intravenous solutions which are designed to be tamper-evident and which show no evidence that tampering has occurred may be returned to stock. Medications that leave the medical institution or its legal affiliates may not be returned to stock for redispensing.

(8) The licensed pharmacist who directs pharmacy services in the medical institution shall make the policies, procedures, and written reports required by this rule available to the board of pharmacy, upon request.

History: 1979 AC; 1980 AACS; 1998-2000 AACS.

R 338.487 Rescinded.

History: 1954 ACS 37, Eff. Feb. 14, 1964; rescinded 1954 ACS 86, Eff. Jan. 7, 1976.

R 338.488 Standard clinical thermometers.

Rule 18. (1) In addition to meeting the standards approved by the board in subrule (2) of this rule, standard clinical thermometers shall be in compliance in all respects with standards set forth in section 469 of Act No. 328 of the Public Acts of 1931, as amended, being S750.469 of the Michigan Compiled Laws.

(2) The board approves and adopts by reference the standards for manufacturing clinical thermometers approved by the American society for testing and materials on August 29, 1986, and issued under the

designation "E 667-86." Copies of the standards may be obtained, at no cost, from either the Board of Pharmacy, P.O. Box 30018, Lansing, Michigan 48909, or the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pennsylvania 19103.

(3) To obtain certification, a manufacturer shall submit a completed application, on a form provided by the department, together with the requisite fee and 2 representative samples of each type or kind of thermometer which the manufacturer desires to offer for sale in Michigan.

The manufacturer shall submit additional representative samples if requested by the board. If the board finds that the samples comply with the requirements of this rule, the board shall certify the thermometers for sale in Michigan and the department shall issue a certification to the manufacturer.

(4) Upon request, a manufacturer shall provide a signed guarantee that the standard clinical thermometers offered for sale in Michigan were certified by the manufacturer to comply with subsection 469(2) of Act No. 328 of the Public Acts of 1931, as amended, being S750.469(2) of the Michigan Compiled Laws, and this rule. A manufacturer that is issued a certification by the board shall package each standard clinical thermometer in a container that prominently displays a notification that the thermometer meets the manufacturing standards approved by the board.

The notification shall be printed either on the package or the package insert.

History: 1979 AC; 1982 AACS; 1988 AACS; 1990 AACS.

R 338.489 Automated devices.

Rule 19. (1) An automated device means a device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription.

(2) An automated device may be used only in the following locations:

- (a) A pharmacy.
- (b) A hospital.
- (c) A county medical care facility.
- (d) A hospice.
- (e) A nursing home.

(f) Other skilled nursing facility as defined in 1978 PA 368, MCL 333.20109.

(g) An office of a dispensing prescriber.

(3) An automated device designed for the specific purpose of selling, dispensing, or otherwise disposing of any drug or device ordered by a prescription, as defined in the code, and located within a licensed pharmacy shall be used only by a pharmacist or other pharmacy personnel under the personal charge of a pharmacist.

(4) If an automated dispensing device is used in a dispensing prescriber's office, the device shall be used only to dispense medications to the dispensing prescriber's patients and only under the control of the dispensing prescriber. A pharmacy shall not own, control, or operate an automatic dispensing device in a dispensing prescriber's office.

(a) If a dispensing prescriber delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing

a board-approved error prevention technology that complies with R 338.3154.

(b) A dispensing prescriber operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(c) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the dispensing prescriber for review by an agent of the board. This documentation shall include at least all of the following information:

(i) Manufacturer name and model.

(ii) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(iii) Policy and procedures for system operation that addresses at a minimum all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

(D) Data retention or archival records.

(E) Downtime procedures.

(F) Emergency procedures.

(G) Medication security.

(H) Quality assurance.

(5) An automated device that is to be used for the furnishing of medications for administration to registered patients in any hospital, county medical care facility, nursing home, hospice, or any other skilled nursing facility, as defined in 1978 PA 368, MCL 333.20109, shall be supplied and controlled by a pharmacy that is licensed and located in this state. The use of an automated device in these locations is not limited to the provisions of subrule (3) of this rule. If a pharmacist delegates the stocking of the device, then technologies shall be in place and utilized to ensure that the correct drugs are stocked in their appropriate assignment utilizing board-approved error prevention technology that complies with R 338.3154.

Each such device shall comply with all of the following provisions:

(a) A pharmacy operating an automated device is responsible for all medications that are stocked and stored in that device as well as removed from that device.

(b) If any medication or device is dispensed from an automated device, then documentation as to the type of equipment, serial numbers, content, policies, procedures, and location within the facility shall be maintained by the pharmacy for review by an agent of the board. The documentation shall include at least all of the following information:

(i) Name and address of the pharmacy responsible for the operation of the automated device.

(ii) Name and address of the facility where the device is located.

(iii) Manufacturer name and model number.

(iv) Quality assurance policy and procedure to determine continued appropriate use and performance of the automated device.

(v) Policy and procedures for system operation that address at a minimum

all of the following:

(A) Accuracy.

(B) Patient confidentiality.

(C) Access.

- (D) Data retention or archival records.
  - (E) Downtime procedures.
  - (F) Emergency procedures.
  - (G) Medication security.
  - (H) Quality assurance.
  - (I) Ability to provide on demand to an agent of the board a list of medications qualifying for emergency dose removal without pharmacist prior review of the prescription or medication order.
- (6) Records and electronic data kept by automated devices shall meet all of the following requirements:
- (a) All events involving access to the contents of the automated devices shall be recorded electronically.
  - (b) Records shall be maintained for 5 years by the pharmacy and shall be retrievable on demand for review by an agent of the board. The records shall include all of the following information:
    - (i) The unique identity of device accessed.
    - (ii) Identification of the individual accessing the device.
    - (iii) The type of transaction.
    - (iv) The name, strength, dosage form and quantity of the drug accessed.
    - (v) The name of the patient for whom the drug was ordered.
    - (vi) Identification of the pharmacist responsible for the accuracy of the medications to be stocked or restocked in the device.
  - (7) Policy and procedures for the use of the automated device shall include a requirement for pharmacist review of the prescription or medication order before system profiling or removal of any medication from the system for immediate patient administration. This subrule does not apply to the following situations:
    - (a) The system is being used as an after-hours cabinet for medication dispensing in the absence of a pharmacist as provided in R 338.486(4)(i).
    - (b) The system is being used in place of an emergency kit as provided in R 338.486(4)(c).
    - (c) The system is being accessed to remove medication required to treat the emergent needs of a patient as provided in R 338.486(4)(c). A sufficient quantity to meet the emergent needs of the patient may be removed until a pharmacist is available to review the medication order.
    - (d) In each of the situations specified in subdivisions(a)to c) of this subrule, a pharmacist shall review the orders and authorize any further dispensing within 48 hours.
    - (e) The device is located in a dispensing prescriber's office.
  - (8) A copy of all policies and procedures related to the use of an automated device shall be maintained at the pharmacy responsible for the device's specific location or at the dispensing prescriber's office and be available for review by an agent of the board.

History: 1979 AC; 1980 AACS; 2007 AACS.

R 338.490 Professional responsibility; "caregiver" defined.

Rule 20. (1) A pharmacist has a professional responsibility for the strength, quality, purity, and the labeling of all drugs and devices dispensed under a prescription. In discharging this responsibility, a pharmacist shall utilize only those drugs and devices that are obtained from manufacturers and wholesale distributors

licensed under section 17748 of the code or from other lawful channels of distribution.

(2) A pharmacist shall not fill a prescription order if, in the pharmacist's professional judgment, any of the following provisions apply:

- (a) The prescription appears to be improperly written.
- (b) The prescription is susceptible to more than 1 interpretation.
- (c) The pharmacist has reason to believe that the prescription could cause harm to the patient.

(d) The pharmacist has reason to believe that the prescription will be used for other than legitimate medical purposes.

(3) A prescription drug shall only be dispensed when the pharmacy is open and under the personal charge of a pharmacist.

(4) To encourage intended, positive patient outcomes, a pharmacist shall communicate, to the patient or the patient's caregiver, necessary and appropriate information regarding safe and effective medication use at the time a prescription is dispensed. As used in this subrule, "caregiver" means the parent, guardian, or other individual who has assumed responsibility for providing a patient's care. All of the following provisions apply to communicating medication safety and effectiveness information:

(a) The information shall be communicated orally and in person, except when the patient or patient's caregiver is not at the pharmacy or when a specific communication barrier prohibits oral communication. In either situation, providing printed material designed to help the patient use the medication safely and effectively satisfies the requirements of this subrule.

(b) The information shall be provided with each prescription for a drug not previously prescribed for the patient.

(c) If the pharmacist deems it appropriate, the information shall be provided with prescription refills.

(d) The information shall be provided if requested by the patient or patient's caregiver or agent for any prescription dispensed by the pharmacy.

This subrule does not require that a pharmacist provide consultation if a patient or a patient's caregiver refuses consultation. This subrule does not apply to prescriptions dispensed for administration to a patient while the patient is in a medical institution.

(5) Pharmacist delegation of acts, tasks, or functions shall be in compliance with section 16215 of the code and under the personal charge of the delegating pharmacist, except as provided in R 338.486(3). A pharmacist who delegates acts, tasks, or functions to a licensed or unlicensed person shall do all of the following:

(a) Determine the knowledge and skill required to safely and competently complete the specific act, task, or function to be delegated.

(b) Before delegating an act, task, or function, makes a determination that the delegatee has the necessary knowledge and skills to safely and competently complete the act, task, or function.

(c) Provide written procedures or protocols, or both, to be followed by the delegatee in the performance of the delegated act, task, or function.

(d) Supervise and evaluate the performance of the delegatee.

(e) Provide remediation of the performance of the delegatee if indicated.

(6) A delegating pharmacist shall bear the ultimate responsibility for the performance of delegated acts, tasks, and functions performed by the delegatee within the scope of the delegation.

History: 1979 AC; 1990 AACS; 1998-2000 AACS.

R 338.491, R 338.492 Rescinded.

History: 1954 ACS 37, Eff. Feb. 14, 1964; rescinded 1954 ACS 77, Eff. Sept. 26, 1973.

## PART 2. MANUFACTURING AND DISTRIBUTION OF PRESCRIPTION DRUGS

R 338.493a Applicability; distributions by pharmacies; license requirements.

Rule 23a. (1) These rules apply to a manufacturer or wholesale distributor that is licensed to do business in this state on or after September 1, 1992, or that applies for a license to do business in this state on or after September 1, 1992.

(2) If the total number of dosage units of all prescription drugs that are distributed by a pharmacy to a person as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the 12-month period, then the pharmacy is a wholesale distributor as defined in section 17709(2) of the code.

(3) If the total number of dosage units of all prescription drugs that are prepared or compounded by a pharmacy for resale, compounding, or dispensing by another person, as defined in section 1106 of the code, during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the 12-month period, then the pharmacy is a manufacturer as defined in section 17706(1) of the code.

(4) A manufacturer or wholesale distributor that distributes prescription drugs in Michigan only from a location outside of Michigan shall obtain a license to do business in Michigan. A manufacturer or wholesale distributor that manufactures or distributes prescription drugs in Michigan from 1 or more locations in Michigan shall obtain a separate license for each location in Michigan where prescription drugs are manufactured or distributed.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.493b Manufacturing practice; adoption by reference of standards.

Rule 23b. A manufacturer shall maintain the building, operate the equipment, and administer the controls, records, and methods used for, and in connection with, the manufacturing, processing, packing, labeling, holding, and distributing of all prescription drugs in conformity with current good manufacturing practice pursuant to the criteria set forth in the provisions of 21 C.F.R. SS211.1 to 211.208, (April 1, 1979). The criteria set forth in the provisions of 21

C.F.R. SS211.1 to 211.208 are adopted in these rules by reference. Copies of the adopted material are available from the Superintendent of Documents, United States Government Printing Office, Washington, DC 20402, at a cost as of the time of adoption of these amendatory rules of \$4.00 or from the Board of Pharmacy, Department of Commerce, P.O. Box 30018, Lansing, Michigan 48909, at a cost as of the time of adoption of these amendatory rules of \$4.00.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493c Wholesaling practice; minimum requirements.

Rule 23c. A wholesale distributor shall maintain and comply with all of the following minimum standards for the storage and handling of prescription drugs and the establishment and maintenance of prescription drug distribution records:

(a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall be in compliance with all of the following provisions:

(i) Be of a suitable size and construction to facilitate cleaning, maintenance, and proper operations.

(ii) Have storage areas that are designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(iii) Have a quarantine area for the storage of prescription drugs which are outdated, damaged, deteriorated, misbranded, or adulterated or which are in immediate or sealed secondary containers that have been opened.

(iv) Be maintained in a clean and orderly condition.

(v) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) All facilities that are used for wholesale drug distribution shall be secure from unauthorized entry as specified in the following provisions:

(i) Access from outside the premises shall be kept to a minimum and be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(ii) All facilities shall be equipped with an alarm system to detect entry after hours.

(iii) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with label requirements or in accordance with requirements set forth in the current edition of the official compendium. If storage requirements are not established for a prescription drug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document the proper storage of prescription drugs. The recordkeeping requirements in subdivision (f) of this rule shall be followed for all stored

prescription drugs. (d) All of the following provisions apply to the examination of materials:

(i) Each outside shipping container shall be visually examined upon receipt for the identity of the prescription drug products and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damages to the contents.

(ii) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that prescription drugs that have been damaged in storage or held under improper conditions are not delivered.

(iii) The recordkeeping requirements in subdivision (f) of this rule shall be followed for all incoming and outgoing prescription drugs.

(e) All of the following provisions apply to returned, damaged, and outdated prescription drugs:

(i) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(ii) Any immediate or sealed outer or sealed secondary containers of any prescription drugs that have been opened or used shall be identified as such and the drugs shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(iii) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(iv) The recordkeeping requirements of subdivision (f) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) All of the following provisions apply to recordkeeping:

(i) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include all of the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received and distributed or disposed of.

(c) The dates of receipt and distribution or other disposition of the drugs.

(ii) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of 2 years after disposition of the drugs.



(iii) Records which are described in this subdivision and which are kept at the inspection site or can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records which are kept at a central location apart from the inspection site and which are not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(g) Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include all of the following procedures in their written policies and procedures:

(i) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedures may permit deviation from this requirement if the deviation is temporary and appropriate.

(ii) A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(a) Any action initiated at the request of the food and drug administration, the board, or other federal, state, or local law enforcement agency or other government agency.

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market.

(c) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(iii) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle, any crisis that affects security or operation of any facility in the event of strike, fire, flood, other natural disaster, or other situations of local, state, or national emergency.

(iv) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) Wholesale distributors shall establish and maintain lists of officers, directors, managers, and other persons who are in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) Wholesale distributors shall operate in compliance with applicable federal, state, and local laws and regulations and permit representatives of the board and other authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and audit their records and written operating procedures at reasonable times and in a reasonable manner.

(j) Wholesale distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(k) Each person employed in any prescription drug wholesale distribution activity shall have education, training and experience, or any combination of education, training and experience, sufficient for

that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493d License application; manufacturers and wholesale distributors.

Rule 23d. An application for a license as a manufacturer or wholesale distributor shall be made on a form provided by the department and shall contain all of the following information:

(a) All names, addresses, and telephone numbers used by the applicant in this state.

(b) State of incorporation.

(c) The kind of ownership or operation, such as individually owned, partnership, association, cooperative, or corporation.

(d) The name of the owner or operator, including, in the case of a partnership, the name of each partner and, in the case of a corporation, the name and title of each corporation officer and director.

(e) A partnership, corporation, or an applicant who operates under an assumed name shall file certified copies of its partnership certificate, corporate articles, or assumed name certificate with its initial application.

(f) A brief description of the buildings in this state that are owned, controlled, or used by the applicant in connection with, or for the manufacture or wholesale distribution of, prescription drugs, the address, if different from that of the principal address of the applicant, at which each building is located, and an indication of the type of activity or activities carried on in each building, such as any of the following:

(i) The manufacture of active ingredients.

(ii) Compounding.

(iii) Packaging.

(iv) Repackaging.

(v) Operating a quality control laboratory.

(vi) Recordkeeping and storage.

(vii) Operating a sales office.

(viii) Warehousing of ingredients.

(ix) Warehousing of finished products for distribution.

(g) An applicant for a manufacturer's license shall also furnish information as to the formula and name or names of each prescription drug that is supplied or distributed under the manufacturer's label. An up-to-date catalog that contains information required by this subdivision may be supplied for this purpose.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493e Rescinded.

History: 1979 AC; 1980 AACS; 1992 AACS; 1998-2000 AACS.

R 338.493f Inspection of applicants and licensees.

Rule 23f. The board or a board inspector may enter, at reasonable times, any building, place, or facility which is owned or controlled by any applicant for, or holder of, a license to make an inspection which is reasonably necessary to enable the board to determine whether the applicant possesses the necessary qualifications and competence for the license sought or to determine whether a license holder is, and has been, complying with the acts and rules enforced by the board. The inspection shall be carried out in a reasonable manner and shall concern only matters relevant to the applicant's or license holder's manufacturing or wholesale distributing of drugs saleable on prescription only. The inspection shall not extend to any of the following information:

- (a) Financial data.
- (b) Sales data other than shipment data.
- (c) Pricing data.
- (d) Personnel data other than data as to the qualifications of personnel performing functions subject to the acts and rules enforced by the board.
- (e) Research data.

History: 1979 AC; 1980 AACS.

R 338.493g Persons to whom drugs may be sold or distributed.

Rule 23g. With respect to prescription drugs, a manufacturer or wholesale distributor shall only supply, distribute, sell, offer for sale, barter, or otherwise transfer drugs to persons who are licensed by the board or to persons who are licensed to prescribe drugs in this state.

History: 1979 AC; 1980 AACS; 1992 AACS.

R 338.493h Rescinded.

History: 1979 AC; 1980 AACS.

R 338.494 Rescinded.

History: 1979 AC; 1982 AACS; 1988 AACS.

R 338.495 Rescinded.

History: 1979 AC; 1988 AACS; 1998-2000 AACS.

R 338.496 Rescinded.

History: 1979 AC; 1998-2000 AACS.

R 338.497 Assessment of fines.

Rule 1. (1) When a fine has been designated as an available sanction for a violation of section 16221 to section 16226 of the code, in the

course of assessing a fine, a board shall take into consideration the following factors without limitation:

(a) The extent to which the licensee obtained financial benefit from any conduct comprising part of the violation found by the board.

(b) The willfulness of the conduct found to be part of the violation determined by the board.

(c) The public harm, actual or potential, caused by the violation found by the board.

(d) The cost incurred in investigating and proceeding against the licensee.

(2) A fine shall not exceed the sum of \$5,000.00 for each violation found to have been committed by the licensee.

History: 1981 AACs.

### PART 3. MEDICATION DRUG BOX EXCHANGE PROGRAMS FOR HOSPICE

R 338.500 Hospice emergency drug box.

Rule 30. (1) A pharmacy that establishes a medication box exchange program for hospice emergency care services rendered in patients' homes pursuant to the provisions of section 17746 of the code shall establish drug boxes that are in compliance with this rule. Before providing drug boxes for a hospice emergency care system, the pharmacist in charge shall assure that the hospice has developed policies and procedures that require all of the following:

(a) Maintenance by the hospice of a drug box exchange log that accounts for the hospice's receipt of the boxes from the pharmacy, assignment of the boxes to registered nurses or physicians' assistants, and return of the boxes to the pharmacy for restocking.

(b) A procedure to assure that the drug boxes are inspected at least weekly to determine if they have expired or have been opened.

(c) Procedures for the storage and control of a drug box while it is assigned to, and being used by, a registered nurse or physician's assistant.

(d) A procedure for implementing the hospice medical director's responsibility for assuring that prescriptions for drugs removed from the drug boxes are obtained from the attending physicians.

(2) A pharmacy shall stock drug boxes for a hospice emergency care system in accordance with the policies and procedures developed by the hospice and approved by the hospice medical director.

(3) The drugs contained in each drug box shall be listed inside the front cover of the box. Each box shall be equipped with only 1 nonreusable, tamper-evident seal or sealing system which is a color that designates that the box has not been opened and several nonreusable, tamper-evident seals or sealing systems which are a different color that designates that the box has been opened.

(4) The drug boxes shall be numbered. A permanent record of all drug boxes shall be maintained at the pharmacy.

(5) A label that contains all of the following information shall be attached to the drug box so that it is visible from the outside of the box:

(a) The name and address of the pharmacy.

(b) The name and address of the hospice.

(c) The name of the pharmacist who last inspected and restocked the drug box.

(d) The date the drug box was last restocked.

(e) The date on which the drug box must be returned to the pharmacy for the replacement of expired drugs.

(f) The number of the drug box.

(6) After the drug box has been stocked and labeled, the pharmacist shall seal it with the nonreusable, tamper-evident seal or sealing system which is the color that designates that the box has not been opened.

(7) The drug boxes shall be kept in a substantially constructed, securely locked storage compartment when not under the direct control of the pharmacist, registered nurse, or physician's assistant. The boxes shall be stored under conditions that will maintain the stability, integrity, and effectiveness of the drugs. Access to the storage compartment shall be limited to individuals who are authorized to dispense drugs from a drug box on the order of an attending physician or the hospice medical director.

(8) The drug box shall remain sealed at all times, except when in use. The drug box shall only be opened by a registered nurse or physician's assistant on the order of an attending physician or the medical director of the hospice. All drugs removed from the box shall be recorded on a medication use form. After completing the form, the registered nurse or physician's assistant shall place the form in the box and seal the box with a nonreusable, tamper-evident seal or sealing system which is a color that designates that the box has been opened.

(9) Each drug box under the control of the pharmacy shall be examined at least weekly to assure that the seal which designates that the box has not been opened is still intact and the expiration date has not been exceeded. If the expiration date has been exceeded or the box has been opened, the box shall be returned to the pharmacy. When written prescriptions are required, the prescriptions of the attending physician or hospice medical director shall accompany the drug boxes that have been opened when the drug boxes are returned to the pharmacy.

(10) The pharmacy shall maintain a permanent record of drug box exchanges on a drug box exchange log. The record shall contain all of the following information:

(a) The number of the box.

(b) The name of the hospice to which the box is released.

(c) The date the box is released to the hospice.

(d) The name and signature of the pharmacist who releases the box to the hospice.

(e) The expiration date assigned.

(f) The date the box is returned to the pharmacy for restocking.

(g) The name and signature of the pharmacist who received the box for restocking.

(11) Upon return of the drug box to the pharmacy, the pharmacist shall reconcile the drugs dispensed from the drug box with the prescriptions of the attending physician or medical director of the hospice. The pharmacist shall note that the prescriptions were dispensed from the hospice drug box on the back of the prescriptions. The prescriptions shall be filed in the same manner as other prescriptions are maintained at the pharmacy.

History: 1995 AACs.